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American Water Works Association

Dedicated to Safe Drinking Water 1401 New York Avenue, NW Suite 640
Washington, DC 20005

January 9, 2004

Water Docket
Environmental Protection Agency, Mail Code 4101T
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Long-Term 2 Enhanced Surface Water Treatment Rule, Proposed Rule, 68 Federal Register 47639, Docket No. OW–2002–0039

Dear Sir or Madam:

The American Water Works Association (AWWA) appreciates the opportunity to review the Proposed Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) that EPA released on August 11, 2003 (68 Federal Register 47639). We believe that the attached comments are much more constructive because the agency extended the comment period for the proposal (68 Federal Register 58057), giving our volunteers and staff time for a more thorough analysis.

We affirm our support for the Stage 2 M/DBP Agreement in Principle (AIP) developed by the Stage 2 Microbial/Disinfection By-Product (M/DBP) Federal Advisory Committee (FACA) and the basic components of that AIP that are reflected in the LT2ESWTR proposal: (1) monitoring of *Cryptosporidium* to facilitate bin determinations, (2) the binning algorithm and specific bin boundaries, (3) the microbial toolbox, and (4) the implementation sequence.

AWWA reviewed the Federal Register notice and supporting documents for the proposed LT2ESWTR, the Agreement in Principle (AIP) and the relevant sections of the Safe Drinking Water Act (SDWA). In our comments, we identify many areas of substantial agreement. Additionally, we believe our recommended technical revisions will substantially improve implementation of this rulemaking.

AWWA is very concerned that the agency's Economic Analysis documents and preamble text have created an unrealistic expectation and implied a significantly greater benefit than will actually be realized through implementation of the LT2ESWTR. The projected risk of endemic cryptosporidiosis creates a perception of certainty that is then reflected in the urgency of the implementation schedule, the microbial toolbox, and other rule requirements. This consistent stringency in the microbial toolbox is a fundamental flaw in the proposal, as the restrictive operational and reporting requirements are out of balance with the uncertainties surrounding the endemic *Cryptosporidium* risk. The LT2ESWTR is a proactive step by the drinking water utility community to further enhance public health in the face of this uncertainty.

AWWA has identified four major aspects of the proposal that require revision:

1. Failure to meet the proposed requirement for consecutive monthly samples must not trigger placement of a water treatment plant into Bin 4.
2. EPA is obligated under the Agreement in Principle to publish in the Federal Register a formal finding with supporting documentation to demonstrate adequate laboratory capacity for the required *Crytosporidium* and *E. coli* monitoring prior to promulgation of LT2ESWTR. The agency's demonstration of available laboratory capacity must be subject to public notice and comment through a Notice of Data Availability (NODA) prior to the promulgation of LT2ESWTR.
3. EPA should re-evaluate the toolbox technologies with the objective of assigning sound and operationally achievable credits for each toolbox element. The agency should pay particular attention to providing credit for watershed protection, enhanced filtration (i.e., peer review or individual filter credits and combined filter effluent credits), bank filtration, and demonstration of performance.
4. EPA should reconsider the layers of safety factors and conservative assumptions that the UV guidance document reflects to ensure that application of this technology is feasible for LT2ESWTR compliance.

AWWA appreciates the ongoing spirit of cooperation with EPA in the development of this complex rulemaking. We appreciate your review and consideration of this letter and the attached detailed comments. If you have any questions regarding this letter or the attached comments, please contact me at (202) 628-8303.

Best regards,

-- / Signed 1/9/2004 / --

Thomas W. Curtis
Deputy Executive Director

cc: Cynthia Dougherty—USEPA OGWDW
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Dan Schmelling—USEPA OGWDW

Formal Comments
of the
American Water Works Association

on the
Long-Term 2 Enhanced Surface Water Treatment Proposed Rule

68 Federal Register 47639, August 11, 2003

Submitted to: Water Docket, OW-2002-0039

January 9, 2004

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Comments of the American Water Works Association on the Long-Term 2 Enhanced Surface Water Treatment Proposed Rule

68 Federal Register 47639, August 11, 2003, Docket No. OW–2002–0039

1 Executive Summary

The American Water Works Association (AWWA) is an international non-profit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Our 56,000 members include more than 4,600 utilities that supply roughly 80 percent of the nation's drinking water. AWWA was one of the national associations representing the drinking water community in the Stage 2 Microbial/Disinfection By-Product Federal Advisory Committee (Stage 2 M/DBP FACA) as well as previous FACA processes on the regulation of Disinfection By-Products (DBPs) and *Cryptosporidium*.

AWWA continues to support the Stage 2 M/DBP FACA Agreement in Principle. AWWA commends the U.S. Environmental Protection Agency (EPA) for the enormous effort undertaken to prepare the proposed rule and the supporting documents. AWWA appreciates the efforts of EPA in issuing multiple draft guidance documents in conjunction with the rule proposal as requested by the stakeholders in the Agreement in Principal. Our comments on the rule proposals do not include detailed comments on the guidance documents. Rather, we assume that as the regulatory language is finalized and the guidance documents are revised, AWWA will continue to be included in the guidance document revision process. We look forward to providing additional input to all of the guidance documents.

AWWA's comments are consistent with our continued commitment to the Agreement in Principle as signed on September 25, 2000. AWWA believes that the FACA process for the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) and Stage 2 Disinfectants and Disinfection By-Product Rule (Stage 2 DBPR) was a successful stakeholder endeavor. The purpose of this review is to provide the EPA with recommendations to the LT2ESWTR proposal and the supporting documents. This review is meant to be proactive and constructive by focusing on specific recommendations for the final regulation. This summary highlights our major concerns. More extensive detail is provided in the body of our comments.

1.1 Agreement in Principle

AWWA participated in the Stage 2 M/DBP FACA and signed the Agreement in Principle (AIP) in September 2000 because the FACA recognized the considerable uncertainties in the available information on these issues and reflected those uncertainties in a limited, but proactive, set of regulatory recommendations. AWWA remains fully committed to the execution of the spirit and intent of the Stage 2 M/DBP FACA's recommendations as stated in the Agreement in Principle.

With three important exceptions, AWWA believes EPA faithfully reflected the Stage 2 M/DBP FACA AIP with the proposed LT2ESWTR. The three inconsistent components of the proposed LT2ESWTR are:

1. Failure to meet the proposed requirement for consecutive monthly *Cryptosporidium* samples triggers automatic placement of a treatment plant into the bin with the strictest treatment requirements (Bin 4);
2. The proposal briefly mentions laboratory capacity but does not include a demonstration of adequate laboratory capacity for the required *Crytosporidium* and *E. coli* monitoring; and
3. The EPA has been overly restrictive in its specifications for proper design and implementation of microbial toolbox elements. The agency did not achieve the AIP's intention of flexible solutions to bin determinations.

1.2 Notice of Data Availability

AWWA recommends that the agency publish a Notice of Data Availability (NODA) that includes these subjects:

1. An assessment of laboratory capacity,
2. A capacity development plan or a plan to extend the sampling period to accommodate the limited capacity, if the agency deems there is inadequate laboratory capacity,
3. Provision of an adequate period of time for utilities to prepare the sampling plan, and an adequate period for the primacy agency (EPA regional offices or state primacy agencies) to review and approve the plan,
4. A description of the status and adequacy of the data management system, and
5. A plan for EPA regional offices to make bin determinations, if state primacy is lacking at the time such determinations need to be made.

1.3 Source Water Monitoring and Data

The specific regulatory language on "source water monitoring" presents challenges to utilities with respect to sampling locations and schedules. AWWA recommends that EPA clarify that the intent of monitoring is to characterize water as it enters the conventional treatment train (influent water). EPA should also modify the compliance schedule to incorporate review and approval of the LT2ESWTR monitoring plan by the primacy agency, prior to initiation of the required monitoring.

AWWA is concerned that EPA's desire to ensure unbiased *Cryptosporidium* data has led to overly prescriptive monitoring requirements. The agency's requirement for two years of monthly sampling as an unbroken record with no gaps in the sampling period is not realistic or feasible on a national scale. EPA's provisions in the proposal for replacement samples, and mechanisms to address unforeseen sampling or analysis problems are inadequate.

AWWA recommends that monitoring plans under §141.701(e) allow make-up sample(s) to compensate for a gap in accepted sampling results. When evaluating previously collected (grandfathered) data, gaps in sequence are likely to occur. The agency should identify the availability of 24, 48, or more samples as a demonstration of data adequacy that allows more flexible use of pre-existing data.

EPA has taken important steps to make improvements to EPA Method 1622 / 1623. A number of these improvements, such as qualifying additional filters and modifying hold times, will facilitate monitoring under the LT2ESWTR. The agency should continue to recognize that EPA Method 1622/1623 is a performance-based method. Therefore, using appropriate validation procedures, modification of the method is appropriate and the resulting data is valid under the LT2ESWTR. In defining performance of EPA Method 1622/1623 and describing the LT2ESWTR data reporting process, EPA has provided an opportunity for utilities to "contest" specific monitoring results. EPA should further elaborate on the data reporting process to provide for (1) appropriate documentation of sample results by laboratories and (2) an administrative review of contested data. Such review should include the involvement of microbiologists with relevant skills and experience.

1.4 Implementation Schedule

The Stage 2 FACA constructed a very aggressive implementation schedule for the LT2ESWTR. As EPA lays out specifics of implementation, the practicality of the schedule reflected in the Agreement in Principle has become more questionable. AWWA believes that implementation would be best accomplished through state primacy agencies, rather than developing a new process through EPA Regions that are less familiar with the utilities. Primacy agency review and approval are needed for the evaluation of pre-existing data for bin determination, and for the defined sampling plan and schedule. Accordingly, AWWA recommends that the rule provide that delays in completing primacy agency review not impact a system's total compliance timeframe of three years, plus an additional two years if needed for capital improvements.

1.5 Microbial Toolbox

In crafting the proposed rule, EPA has focused exclusively on adding additional inactivation or removal. The agency has excluded benefits associated with improving overall treatment stability and performance through improved Combined Filter Effluent (CFE) and Individual Filter Effluent (IFE) performance measures. This focus on inactivation has resulted in a rule structure that encourages utilities only to add ultraviolet light disinfection to achieve regulatory compliance at what EPA considers an "affordable" cost. This endpoint is dramatically different from the Stage 2 M/DBP Agreement in Principle. The Stage 2 M/DBP FACA intended to encourage investment in source water protection and robust treatment alternatives such as membranes and bank filtration, as well as reward utilities that have invested in achieving optimum operating proficiency in their conventional facilities.

1.6 Watershed Control

As currently constructed, the Watershed Control Program (WCP) component of the LT2ESWTR is not a viable toolbox element. The draft guidance creates disincentives through overly restrictive monitoring and reporting requirements, rather than incentives for utilities to engage in source water protection activities. Additionally, utilities currently engaged in source water protection are penalized by having to demonstrate increased water quality improvement over and above current programs, rather than being rewarded and recognized for their proactive effort.

AWWA believes that the Stage 2 M/DBP FACA intended to promote increased investment by drinking water utilities in source water protection. In following through on this recommendation, the agency should develop realistic expectations for watershed control programs. Several years may pass before noticeable changes in water quality are realized. The agency should not impose administrative processes such as the proposed "re-approval cycle" that draw resources away from productive source water protection activities.

1.7 Bank Filtration

AWWA agrees with the proposed rule provisions (§141.726) that allow 0.5 or 1.0-log *Cryptosporidium* credit (§141.720(b)) or upper bin technology credit (§141.720(c)) to utilities that propose to install bank filtration wells. In addition to these requirements, the agency should also explicitly provide for demonstration of additional log credit using a test well. An appropriate study should be adequate to obtain more flexible design criteria, siting, and greater log credit assignment.

1.8 Revision of Enhanced Filter Performance Criteria

The proposed rule defines the Combined Filter Effluent (CFE) credit as a 0.5-log credit and the Individual Filter Effluent (IFE) credit as a 1.0-log credit that cannot be used in combination with the CFE credit. The net maximum is 1.0-log credit. The same net effect can be achieved more simply by defining the two credits as separate 0.5-log credits that can be combined, thereby still resulting in a maximum 1.0-log credit. The proposal of an IFE credit began with the Stage 2 M/DBP FACA's inclusion of "Peer review program (e.g., PSW Phase IV)" in the microbial toolbox. AWWA continues to believe that utilities that participate in peer review programs should receive credit as proposed by the FACA. However, few appropriate programs exist and those are not uniformly available to all utilities. A solution to this dilemma is to eliminate the proposed IFE credit and replace it with a modified CFE credit. A rigorous CFE credit is detailed later in these comments appropriate for a second 0.5-log credit beyond the current 0.5 CFE credit.

1.9 Demonstration of Performance

AWWA believes that the Demonstration of Performance (DOP) provisions as written are inconsistent with good engineering practices for drinking water treatment plant design. A full year of testing is inconsistent with typical pilot-scale testing of two weeks for each quarter or two weeks during challenging raw water quality conditions. Moreover, these provisions do not encourage or facilitate utilities using DOP. Pilot-scale and full-scale testing is routinely used to demonstrate treatment efficacy and treatment system modifications to primacy agencies. AWWA believes that the penalty provision imposed by the DOP guidance when lower than expected removals are observed should be removed. The agency should significantly modify the proposed guidance to follow good engineering practices for water plant design. A number of specific recommendations are provided in the comments, including endorsement of aerobic spores as an indicator of *Cryptosporidium* removal in full and pilot scale studies.

1.10 Ultraviolet Light

Inactivation using ultraviolet light (UV) is the low-cost compliance technology for the LT2ESWTR. The UV Disinfection Guidance Manual must ensure that UV is a usable technology. AWWA believes that the UV Disinfection Guidance Manual represents an important step forward in advancing UV as a drinking water treatment technology. Unfortunately, the redundant safety factors imposed in the guidance, the difficulties in applying the Tier 1 and Tier 2 analyses, validation issues, and the off-specification criteria set in the proposed rule represent significant obstacles to practical and efficient application of UV.

EPA should retain the proposed UV dose table for *Cryptosporidium* and *Giardia lamblia* in the final rule. The UV Disinfection Guidance Manual should be revised to focus on a single decision-making process that ensures that operational UV doses are reliably equal to or greater than the required dose in the rule text. This process has to be articulated in a clear and simple way for ease of implementation, but this process cannot impede the rapid advancement of UV technology in drinking water treatment.

EPA should clarify the off-specification requirement for filtered systems under LT2ESWTR. AWWA believes that off-specification time should be distinct from "down time". The guidance should differentiate from when a reactor is providing treatment but may not be reaching the required UV dose versus when a UV reactor is not providing any treatment at all. Likewise, compliance metrics should be equally fair to systems regardless of the number of UV reactors in operation.

1.11 Ozone

AWWA believes that retention of ozone, as a viable technology was an essential component of the Stage 2 M/DBP Agreement in Principle. AWWA understands and supports the proposed contact-time (CT) table as a balance between the best-available science and development of a CT table that affords a consistent and simply applied safety factor to address outstanding policy concerns.

AWWA recommends that the agency take additional steps to clearly present the CT requirements, and further refine draft guidance regarding compliance calculations for ozone CT. EPA requested additional data to support the ozone CT table, and these comments include an analysis of research reflecting synergistic disinfection. In addition to the CT Tables in the proposal, EPA should present CT tables that reflect synergistic disinfection through ozone-chloramine and ozone–free chlorine disinfection in the final rule.

1.12 Economic Analysis

The Economic Analysis (EA) and associated support documentation offer extensive detail and information. However, EPA needs to find a better balance in the support documentation so that it provides not only complete, but also the most critical information to interested and involved parties. To find this balance, EPA should use more fundamental, informative, and simple analyses of core components rather than using more sophisticated approaches for some less important aspects of the EA.

In some critical elements of the EA, the agency makes powerful assumptions that can have significant impacts on the final results of the EA. The agency does not always clearly articulate what assumptions are being made and often presents a one-sided view of relevant uncertainties and data limitations to derive its interpretation. In some instances where the agency has made key assumptions, the supporting analysis lacks sensitivity analyses based on equally or more plausible alternative assumptions.

Our major observations and findings with respect to the EA include:

1. Overall, we believe EPA has considerably overstated the occurrence and risks associated with endemic levels of cryptosporidium in finished waters, and thus the agency overstates the benefits of the proposed rule to a considerable degree. The costs of the rule may also be overstated to some degree.
2. The ICRSS data indicate a much smaller percentage of systems will end up in bins 3 and 4 under the proposed rule than do the analyses based on the ICR data, implying that the net benefits (benefits minus costs) of the proposed rule may be 20% of the high end estimates shown by EPA (all else equal). The ICRSS data are better predictors than the ICR data of what the impact of the rule will be as proposed.[1]
3. EPA applies a Bayesian interpretation to the ICR and ICRSS data that is suspect and driven by unsubstantiated and perhaps extreme assumptions. For example, EPA imposes an assumption that only 1 out of every 1000 "zeroes" observed in the database is truly a zero. The agency is thus estimating occurrence and risk based on a presumption that 999 out of every 1000 observed zeroes in the database are instead one oocyst or more.
4. EPA's exposure assessment is based on considerably over-estimated levels of direct ingestion of CWS-provided waters. Relevant exposures (and, hence, risks) may be overstated by a factor of 2 or 3 when direct ingestion rates for CWS waters, and increased bottled water use, are properly considered.
5. The infectivity dose-response relationship applied by EPA is subject to considerable uncertainty and probably overstates the risk associated with exposures to an infectious oocyst by a significant degree.
    a. The underlying clinical studies are use extremely high doses relative to oocyst levels in finished waters (levels of oocysts ingested of 23,000 to 2.3 billion times higher than now found in finished waters) and rely on extremely small number of subjects and strains (between 14 and 29 subjects, for each of only 3 strains).
    b. The results of the clinical studies are interpreted liberally, based on a "presumed infection" approach that assumes that any subject with symptoms has cryptosporidiosis, even when several of the symptomatic subjects had no documented infection (e.g., via positive oocyst shedding). EPA's risk estimates are overstated to the extent that reported symptoms could be attributable to causes other than cryptosporidiosis.
    c. The results of the clinical studies were interpreted via complex statistical models that are driven by -- and highly sensitive to -- unsubstantiated assumptions. While the modeling approaches used by EPA in the EA

[1] The ICRSS data are more indicative of what the rule's impacts will be because they (1) probably are more accurate than the ICR data (ICRSS results are based on Method 1622/1623 with higher recovery rates than the IFA method applied in the ICR data) and (2) reflect the method (1622/1623) that utilities will apply in their compliance monitoring.

were suggested by the SAB, the obscurity of the presentation and the sensitivity of the results to the model assumptions (e.g., increasing a key estimated mean risk parameter by a factor of 4 or 5 over the level found in the peer reviewed published literature) reveals the need for more transparency, continued scientific discourse, and greater use of sensitivity analyses in portraying the possible risk levels.

6. The extent by which EPA's risk model overstates risks can be viewed, in part, by comparing the agency's estimated number of waterborne cases of cryptosporidiosis at the pre-LT2 baseline to its estimated reduction in cases due to the proposed LT2 rule:
    a. EPA estimates the pre-LT2 baseline (i.e., post IESWTR) is between 60,000 and 111,000 cases per year.
    b. The agency's risk model used for the LT2 rule benefit-cost analysis predicts 256,000 to over 1,000,000 cases per year will be avoided due to the rule as proposed.
    c. Therefore, EPA estimates a reduction in cases that is up to 9+ times higher than the number of cases it has stated exist at baseline.
7. EPA needs to explore the soundness and implications of its questionable assumption that the risk of illness (as well as severity and duration of illness) are independent of dose. The morbidity assessment -- used to project the number, severity, and duration of illnesses due to a possible infection – is based exclusively on results from the Milwaukee outbreak of 1993, where oocyst levels were much higher, exposure durations much longer, and opportunities for secondary spread and exposure more pervasive than anticipated under the endemic low dose exposure context addressed by the proposed rule.
8. EPA's use of an "enhanced" cost of illness (COI) approach to value avoided cases of nonfatal cryptosporidiosis is highly problematic. The approach is a significant departure from standard economics practice, does not appear to have been subjected to expert peer review, and yields results that seem implausible and unrealistic compared to other well-established risk valuation benchmarks.
9. EPA's presentation of regulatory costs and benefits is overly aggregated, and fails to reveal how affordability and net benefits vary across system size categories or across other relevant program elements in the proposed rule (e.g., reservoir covering, filtered versus unfiltered systems).

EPA should follow the basic tenants of its own <u>Guidelines for Economic Analyses</u> in revising the EA to support the final rule. Following these Guidelines the agency should: (1) be explicit regarding its core assumptions, 2) document the basis for those assumptions, and (3) develop some useful sensitivity analyses to evaluate and convey the impact of core uncertainties on the outcomes of the analysis. AWWA believes the net effect of a more robust and transparent analysis will be a lower and more realistic, lower bound estimate of anticipated benefits from the proposal.

1.13 Legal Issues

If the agency were to promulgate the final rule as proposed, AWWA believes that such action would be contrary to law, arbitrary and capricious, and an abuse of discretion for the following reasons:

1. The Safe Drinking Water Act (SDWA) does not authorize EPA to mandate a treatment requirement for failure to monitor.
2. The agency will violate the Administrative Procedures Act (APA) if the agency does not ensure adequate laboratory capacity for *Cryptosporidium* and *E. coli* monitoring as required by the Agreement in Principle.
3. EPA would abuse its discretion if it subjected public water systems to penalties for failure to comply with monitoring requirements during what is an unreasonably short timeframe during a period of limited laboratory capacity.
4. The Economic Analysis (EA) is arbitrary and capricious and an abuse of discretion as it overstates the risk and benefits of the proposed rule, is based on an inappropriate statistical analysis, and understates the compliance costs.

Comments of the American Water Works Association on the Long-Term 2 Enhanced Surface Water Treatment Proposed Rule

68 Federal Register 47639, August 11, 2003, Docket No. OW–2002–0039

2 Introduction

The American Water Works Association (AWWA) is an international non-profit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. AWWA's more than 56,000 members represent the full spectrum of the "drinking water community": treatment plant operators and managers, public health officials, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,600 utilities that supply roughly 80 percent of the nation's drinking water.

The comments provided herein reflect the consensus of the AWWA that, given the depth and breadth of its representation, also reflect the predominant view of the nation's drinking water professionals. It is therefore appropriate that these AWWA comments be heard on behalf of the drinking water community in general.

The following comments in no way conflict with AWWA's commitment to the Agreement in Principles document as signed on September 25, 2000. AWWA believes that the Federal Advisory Committee (FACA) process for the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) and Stage 2 Disinfectants and Disinfection By-Product Rule (Stage 2 DBPR) has been a successful endeavor for all the stakeholders. The purpose of this review is to provide the U.S. Environmental Protection Agency (EPA) with both policy recommendations and specific text revisions to the LT2ESWTR proposal. This review is meant to be proactive and constructive by focusing on specific improvements to the proposal that should be incorporated into the final regulation.

EPA should be commended for the effort undertaken to include all of the disparate data into the proposal. The following comments will address areas where AWWA believes that the agency's efforts successfully integrated the available information within the framework of the Stage 2 M/DBP Agreement in Principle and where the agency's effort requires additional work.

3 Agreement in Principle

3.1 AWWA Commitment to the Agreement in Principle

On December 29, 2000, EPA published a Federal Register notice describing the Stage 2 Microbial/Disinfection By-Products Federal Advisory Committee Act (Stage 2 M/DBP FACA) process, why the FACA was convened, and published the Agreement in Principle that was developed and approved by the FACA. In that preamble notice, EPA summarized the FACA recommendations as follows:

> "Despite the evaluation of a large amount of data, the Committee recognized that uncertainty remains in a number of areas regarding the precise nature and magnitude of risk associated with DBPs and pathogens in drinking water. In light of this uncertainty, the Committee recommended a series of balanced steps to address the areas of greatest health concern, taking into careful consideration the costs and potential impacts on public water systems."[2]

This summary statement by EPA is an extraordinarily clear statement of the Stage 2 M/DBP FACA's intent in the Agreement in Principle. Indeed, this summary reflects the FACA discussion from its initiation at the orientation meeting in December 15-16, 1998. Based on the meeting summary, the FACA discussion reflected on the following points:

- Though deadlines for the completion of the ICR and other research activities have slipped, the schedule for rule development is required in the 1996 SDWA Amendments.
- Though the 1996 SDWA Amendments require that EPA perform a cost/benefit analysis, the new provisions do not require EPA to base the Stage 2 regulations on economic analysis.
- It will be important during the Stage 2 process to be realistic about what data will be available for consideration and what uncertainties remain."[3]

The importance of these points is that the LT2ESWTR was developed on substantially the same scientific basis as the IESWTR, save the availability of the ICR data. Note in particular the third bullet.

AWWA was an active participant in the Stage 2 M/DBP FACA and a signatory to the Agreement in Principle. In signing the Agreement in Principle, AWWA agreed to the following provision:

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[2] 65 Federal Register 83017, M/DBP FACA Agreement in Principle. Note this statement directly follows a summary of the data collection effort undertaken in support of the FACA including enumeration of *Cryptosporidium* oocyst occurrence, DBP occurrence, and health risks associated with DBPs.

[3] RESOLVE, Stakeholder Orientation Meeting, December 15-16, 1998, Park Hyatt, Washington, DC, Final Meeting Summary March 1, 1999

> "Each party and individual signatory that submits comments on the Stage 2 DBPR and LT2ESWTR proposals agrees to support those components of the proposals that reflect the recommendations contained in this Agreement in Principle."[4]

The Agreement also specified:

> "Each party agrees not to take any action to inhibit the adoption of final rule(s) to the extent it and corresponding preamble(s) have the same substance and effect as the elements of the Agreement in Principle Part A or Part B or both parts as evidenced by the signature following each part."[5]

AWWA participated in the Stage 2 M/DBP FACA and in September 2000, signed the Agreement in Principle because the FACA recognized the considerable uncertainties in the available information and reflected those uncertainties in its limited but proactive recommendations. AWWA remains fully committed to the execution of the spirit and intent of the Stage 2 M/DBP FACA's recommendations as stated in the Agreement in Principle. AWWA submits these comments to assist EPA in promulgating a final regulation that is consistent with the Stage 2 M/DBP Agreement in Principle. AWWA recommends that the agency adequately characterize the proactive nature of this rulemaking in the face of an uncertain risk in the preamble of the final rule. AWWA recommends that the agency reflect this balance both when the agency is finalizing the specific regulatory requirements and when it communicates the costs and benefits of this rule to drinking water utilities, primacy agencies, and the public.

3.1.1 Bin Structure

AWWA has a number of concerns about the agency's Economic Analysis (EA) that have implications for how the agency describes specific rule requirements and communicates the LT2ESWTR to the public. As previously stated, these concerns do not alter AWWA's commitment to the Agreement in Principle and, in particular, the bin boundaries identified in the Agreement in Principle and reflected in the proposed rule. The bin structure recommended by the FACA constitutes a sound basis for final promulgation of LT2ESWTR. AWWA anticipates that future research on *Cryptosporidium* occurrence and infectivity will inform EPA and the water community whether restructuring the bins is necessary in a future rulemaking.

3.2 Shared Objectives and Principles

Inherent to the Stage 2 M/DBP Agreement in Principle were a number of underlying shared objectives and operating principles. AWWA believes EPA should reflect the principles below in the final LT2ESWTR

3.2.1 Maintaining a Balanced Approach to Treatment

For microbial pathogens, the Stage 2 M/DBP FACA recognized that systems with poor quality source waters might need to provide additional protection against *Cryptosporidium*. This concept is captured in the overall regulatory framework for the LT2ESWTR. The FACA also provided guidance about appropriate treatment barriers for systems that fell within specific source water *Cryptosporidium* oocyst occurrence "bins." In recommending these treatment

[4] 65 Federal Register 83017, M/DBP FACA Agreement in Principle, Section 2.3
[5] 65 Federal Register 83017, M/DBP FACA Agreement in Principle, Section 2.9

alternatives, the FACA was concerned with maintaining a balanced approach to enhancing treatment given the uncertainty in the available data on occurrence and associated risk. Consequently, the FACA weighed five factors in recommending particular treatments in LT2ESWTR:

1. Data on *Cryptosporidium* oocyst removal.
2. Effectiveness as an additional barrier to *Cryptosporidium* oocysts reaching finished water.
3. Other benefits such as
    - Reducing peaks in occurrence of pathogens,
    - Making other processes more stable or effective, and
    - Reducing other contaminants (i.e. TOC, DBP formation), etc.
4. Encouraging use of a variety of technologies.
5. Ensuring viable treatment alternatives to UV disinfection.

Each of the toolbox items has particular strengths among these five factors. Consequently, the microbial toolbox is described in terms of "log credit" reflecting that inclusion in the toolbox reflected a variety of factors other than explicit removal/inactivation of oocysts.

In crafting the proposed rule, EPA has focused exclusively on adding additional demonstrated inactivation or removal, and has excluded benefits associated with overall treatment stability and performance (e.g., increased consistency in plant performance, resilience to upset, greater responsiveness to atypical water quality events). This almost exclusive focus on removal/inactivation has resulted in a rule structure that encourages utilities to add ultraviolet light disinfection as the only technology that assures regulatory compliance at what is projected to be an “affordable” cost. This endpoint is dramatically different from the Stage 2 M/DBP Agreement In Principle. The intent of the Agreement In Principle was to encourage investment in source water protection and robust treatment alternatives such as membranes and bank filtration, to retain ozone feasibility, and to reward utilities that have invested in achieving optimum operating proficiency in their conventional facilities. The following AWWA comments will identify changes that should be made in the final rule to achieve the Stage 2 M/DBP FACA’s objectives.

3.2.2 Range of Options – Not One-Size-Fits-All

The Stage 2 M/DBP FACA's concerns included the diversity of water quality challenges and treatment systems in use, as well as ensuring that water treatment plant improvements at individual utilities are as cost effective as possible and sufficiently flexible to attain multiple drinking water treatment objectives. Indeed, the FACA frequently pointed out the value of combining activities to reduce source water oocyst levels with improvements in treatment at the plant. The FACA members were very concerned that compliance with the LT2ESWTR not be dependent on a single technology, particularly available disinfection technologies, such as ozone and UV disinfection.

Significant barriers continue to impede broad implementation of UV disinfection in the U.S. (i.e., ongoing litigation, lack of certainty regarding validation protocols, lack of state regulator familiarity). In order for utilities to comply with the LT2ESWTR on the required schedule, the LT2ESWTR cannot limit compliance to a single technology.

As currently written, the LT2ESWTR is a UV-disinfection rule. This conclusion is not simply AWWA's informed opinion, as the agency's own cost/benefit analysis further substantiates this conclusion. Exhibit 6.9 Technology Selection Forecast for Filtered Plants in the EA illustrates that UV will dominate LT2ESWTR compliance, and other "tools" will not be employed at more than a handful of water treatment plants. EPA's analysis indicates that more than 70% of PWSs serving greater than 10,000 persons will rely on UV treatment to comply with LT2ESWTR.[6] Additionally, the UV compliance estimates for smaller systems is likely underestimated as the agency's analysis reflects substantial reliance on bag filters (on the order of 1,236 – 1,545 PWSs). This estimate is unrealistic, due to the lack of ongoing performance and integrity testing for bag filters.

3.2.3 Simultaneous Compliance with Stage 2 DBPR

As proposed, the rule schedule reflects simultaneous compliance with the Stage 2 DBPR. AWWA believes that this pairing is critical to the risk-risk balance between DBP and microbial contaminant control. AWWA supports the agency's continued pairing of requirements during initial monitoring and assessment provisions (i.e., source water monitoring and initial distribution system assessment) and final compliance with MCLs and treatment technique requirements.

3.2.4 Balance Between State Flexibility and Agreement in Principle

The proposed LT2ESWTR creates substantial tension between fixed federal requirements and achieving implementation flexibility for States and operating flexibility for utilities. In general, AWWA supports the level of detail provided in the rule language. Similarly, AWWA believes that release of the draft guidance documents in conjunction with the proposed rule substantially improve the public's understanding of the proposed rule provisions.

AWWA believes the guidance documents should use appropriate language to clearly state that guidance is guidance, i.e. the incorporated recommendations are not mandatory. The preamble and guidance documents should reflect a balanced view of treatment alternatives as well as the premises underlying the rule and compliance alternatives. Given the substantial bulk of the guidance manuals, the agency must be careful to avoid imposing regulatory requirements beyond rule provisions through guidance, a prospect that is not legally sound.[7]

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[6] LT2ESWTR Economic Analysis, p.6-23, Note that Exhibit 6.9 reflects a large number of water treatment plants employing bag filtration. Bag filtration is limited in application to very small water treatment facilities; moreover, once utilities attempt to comply with the provisions enumerated in guidance it is unlikely that bag filtration will be a feasible compliance technology under LT2ESWTR.

[7] Barrick Goldstrike Mines Inc. v. Browner, 215 F. 3d 45, DC Cir. 2000, Appalachian Power Company v. Environmental Protection Agency, 200 WL 336911, D.C. Cir. 2000

3.2.5 Retention of Ozone as a Viable Treatment Option

The Stage 2 M/DBP FACA recognized that ozone is an important oxidant in drinking water treatment. Using ozone for disinfection has substantial benefits beyond inactivation of *Cryptosporidium*, including control of other microorganisms, reduction of DBPs, degradation of chemical contaminants, and reduction of offensive taste and odors. The FACA decided that these multiple benefits should continue to be available to utilities under LT2ESWTR and Stage 2 DBPR. Consequently, the performance criteria for *Cryptosporidium* inactivation, in combination with the bromate MCL, should allow a reasonable operating regime for drinking water utilities, particularly where some utilities have proactively invested in ozone before or as a result of the Stage 1 DBPR / IESWTR.

3.3 Adequate Laboratory Capacity for Microbial Monitoring

Adequate documentation of laboratory capacity should have been included in the preamble of the proposed LT2ESWTR. Section 2.11.a. of the Agreement in Principle specifies that:

> *"Compliance schedules for the LT2ESWTR will be tied to the availability of sufficient analytical capacity at approved laboratories for all large and medium affected systems to initiate Cryptosporidium and E. coli monitoring … ."*

The proposed rule does not substantively discuss the availability of commercial laboratory capacity to implement the LT2ESWTR monitoring. Documentation of this capacity is particularly important given the dependence of both the LT2ESWTR and Stage 2 DBPR implementation timelines on the availability of adequate commercial laboratory capacity to support rule implementation.

While EPA acknowledges laboratory capacity as an important issue, the agency fails to provide an estimate of laboratory capacity. The agency must ensure that adequate laboratory capacity exists; failure to do so is a breach of the Agreement in Principle and as such, is not in keeping with the Administrative Procedures Act-Federal Advisory Committee Act, under which the Stage 2 M/DBP FACA was organized. AWWA believes that the agency must provide a robust appraisal of laboratory capacity to support LT2ESWTR prior to promulgation of the final rule. Moreover, AWWA believes that the agency's estimate, methodology, and analysis that substantiate that estimate should be made available for public comment through a Notice of Data Availability (NODA) prior to the promulgation of LT2ESWTR. As is clearly stated in the Agreement in Principle, EPA's laboratory capacity estimate should reflect both *Cryptosporidium* oocyst and *E. coli* sampling.

The agency's duty to develop a robust estimate of laboratory capacity is not only a requirement of the Agreement in Principle, but it is also a sound recommendation for any rule where implementation of compliance requirements is tied to monitoring provisions. Recent experience with the Information Collection Rule provides a relevant example of how unforeseen implementation problems resulted in prolonged delays in data availability.[8] However, the ICR only applied to 297 utilities (population > 100,000) whereas the LT2ESWTR will require more than 1,321 PWS (population >10,000) to collect and report *Cryptosporidium* and *E. coli*

[8] 61 FR 24353, May 16, 1996

monitoring data, and another 8,322 PWSs to start monitoring *E. coli* within 3 years of promulgation.[9]

Currently, 19 laboratories are approved for the protozoan method. Of those 19 laboratories, only 7 are commercial labs. Another way to look at capacity is, if every PWS only had one water treatment plant (an underestimate) six months into the rule implementation, each of the commercial laboratories would have to process approximately half as many samples per month as were processed each month by all of the laboratories that supported the ICR. Neither utilities nor EPA want to see this monitoring component fail and having adequate laboratory capacity is essential to preventing such a failure.

3.4 Notice of Data Availability

AWWA recommends that the agency publish a Notice of Data Availability (NODA) that includes these subjects:

1. An assessment of laboratory capacity,
2. A capacity development plan or a plan to extend the sampling period to accommodate the limited capacity, if the agency deems there is adequate laboratory capacity,
3. Provision of an adequate period of time for utilities to prepare the sampling plan, and an adequate period for the primacy agency (EPA regional offices or state primacy agencies) to review and approve the plan,
4. A description of the status and adequacy of the data management system, and
5. A plan for EPA regional offices to make bin determinations, if state primacy is lacking at the time such determinations need to be made.

AWWA suspects that commercial laboratory capacity is currently inadequate and believes capacity will likely be inadequate at the time of rule promulgation. In the absence of adequate laboratory capacity, AWWA offers the staggered sampling plan below as one approach to addressing the anticipated laboratory capacity shortfall. This plan extends the sampling for source water *Cryptosporidium* over a period of six years. Not only does this reduce the instantaneous demand for laboratory capacity, but it will also promote the likelihood that laboratories will develop staff capabilities to manage the *Cryptosporidium* analytical burden. If a laboratory is assured of having an ongoing analytical business for six years instead of two, investment in additional capacity will be a more attractive business decision for that business.

[9] 2000 Community Water System Survey, Table 1, SDWIS, Surface Water Systems (Surface Water Systems)

Table 1. Example Approach to Staged LT2ESWTR Monitoring

Years	Population Served	Number of Systems	Population Served*
1-2	>50,000	401	120,300,000
3-4	30,000-50,000	460	18,400,000
5-6	10,000-30,000	460	9,200,000

Note: * Population estimates derived from Community Water System Survey and may be underestimates due to assumptions made in CWSS.

This table assumes that the available lab capacity is approximately 33% of what is needed and that the population binning will evenly distribute the load over the six years of sampling. If EPA elects to select this example approach in the final rule, the need for a NODA to address the five issues listed in 3.4 does not change.

AWWA believes an approved sampling plan is necessary for each utility to ensure that the sampling locations chosen by the utility are in accordance with the regulatory requirements. Utilities should not be in a situation where they are notified at the end of the sampling period that samples were taken at an unacceptable location. The schedule for implementation of the rule must provide sufficient time and resources at the primacy agency to allow each utility the opportunity to have its sampling plan reviewed and approved prior to the start of sampling.

AWWA believes that the key to success in implementing the data management software includes:

1. Provision of adequate user training, software documentation, help screens, and a help desk function for the software system.
2. A notification system that will warn EPA, laboratories, and utilities when data are not submitted in a timely manner. This will allow the parties to troubleshoot the data entry process to correct missing or erroneous data.
3. Implementation of an oocyst countdown meter. This meter would indicate how many oocysts could be counted in future samples before the utility reaches the treatment requirements of bin 2, 3, or 4.

AWWA believes that EPA needs to be prepared to assist in future LT2ESWTR implementation in cases where a state has not been granted primacy at the time when a bin determination is needed. EPA will need to engage in dialogue with utilities in states where primacy has not been established and be able to issue a bin determination.

3.5 Agreement in Principle - General Issues

Below are additional general issues that stem from the Agreement in Principle, along with our comments on these issues.

3.5.1 Commitment to Agreement by EPA in the Final Rule

The AIP is limited by providing a generally accepted and agreed upon framework for the proposed LT2ESWTR. However, the AIP does not bind EPA to that framework in the development of the final LT2ESWTR. EPA should recognize that the success of the M/DBP FACA process, and the even broader NDWAC stakeholder process that developed subsequent to the 1996 SDWA Amendments, lies in the agency's following through on such generally agreed frameworks all the way to final rule and implementation guidance.

3.5.2 Responsive to Previous Review of Stakeholder Draft

On December 31, 2001 AWWA submitted comments on a stakeholder draft of the LT2ESWTR. In those comments, AWWA noted the following areas where the draft proposal required additional refinement:

1. Revise the preamble to clearly communicate the interdependence of the uncertainty in estimates of *Cryptosporidium*, the proposed bin structure, and the log credits required in the microbial toolbox.
2. Clarify the basis for the "log credit" concept, which as articulated by the FACA was not limited to "log removal."
3. Expand the preamble to include a more accurate description of *Cryptosporidium* occurrence estimate.
4. Expand the preamble to include estimate of available laboratory capacity.
5. Clarify the grandfathering provisions for *Cryptosporidium* oocyst data.
6. Revise the language on state flexibility so that appropriate balance is maintained between the AIP and state flexibility.
7. Reconsider the small-system binning algorithm based on a six-month running average.
8. Reconsider the ozone and chlorine dioxide CT requirements.
9. Identify ways to simplify LT2ESWTR *Cryptosporidium* oocyst monitoring reporting.
10. Clarify the *Cryptosporidium* oocyst monitoring re-sampling algorithm to allow primacy agency acceptance of an alternative sample taken prior to agency recognition of initial sample date failure.
11. Reflect the recommendations of the National Drinking Water Advisory Council (NDWAC) Workgroup and the Science Advisory Board (SAB) reviews of the arsenic cost/benefit determination and regulatory process processes.

In reviewing the proposal, AWWA found that EPA responded to a number of these concerns. In some instances, the proposal generated new issues and, in other instances, alleviated previous concerns. Areas where the agency has made substantial progress include: (1) handling of small-system binning algorithm, (2) development of CT tables, and (3) developing simplified *Cryptosporidium* oocyst monitoring / reporting. While a number of outstanding issues still remain, two specific issues from the stakeholder draft remain a fundamental concern. The two issues are: (1) the absence of an assessment of laboratory capacity and (2) the agency's failure to craft a fair and implementable microbial toolbox.

3.5.3 UV Representatives

AWWA remains concerned that some representatives to the Stage 2 M/DBP FACA process, with clear financial interests in a single technology (ultraviolet light), participated in the FACA as advocates of this single technology. More importantly, an alternate representative participated in the FACA process without disclosing that his company was simultaneously undertaking an individual corporate strategy to patent the technology the company was advocating as a central component to the Stage 2 M/DBP Agreement in Principle.[10]

AWWA remains concerned that the license fee now required by Calgon Carbon may be a significant impediment to the adoption and use of UV by many water utilities. AWWA strongly encourages EPA to take measures in the crafting of future FACAs to establish ground rules that require full disclosure of business and personal interests so that similar situations are avoided in future FACAs.

3.6 Legal Issues

The following section is meant to provide a simple reference between the technical issues raised in AWWA's comments and the legal setting under which the LT2ESWTR provisions are being developed. If the agency proceeds to promulgate the final rule as proposed, AWWA believes that such action is contrary to law, arbitrary and capricious, and an abuse of discretion for the following reasons:

1. The Safe Drinking Water Act (SDWA) does not authorize EPA to mandate a treatment requirement for failure to monitor.
2. The agency will violate the Administrative Procedures Act (APA) if the agency does not ensure adequate laboratory capacity for *Cryptosporidium* and *E. coli* monitoring as required by the Agreement in Principle.
3. EPA would abuse its discretion if it subjected public water systems to penalties for failure to comply with monitoring requirements during what is an unreasonably short timeframe during a period of limited laboratory capacity.
4. The Economic Analysis (EA) is arbitrary and capricious and an abuse of discretion as the EA overstates the risk and benefits of the proposed rule, is based on a flawed statistical analysis, and understates the compliance costs.

3.7 Implementation Schedule

The Stage 2 D/DBP FACA constructed a very aggressive implementation schedule for the LT2ESWTR. As EPA lays out the specifics of implementation in the stakeholder draft, proposed rule, associated support documents, and in the Draft State Implementation Guidance, the practicality of the schedule reflected in the Agreement in Principle has become more questionable. Of particular concern in the LT2ESWTR are these two issues:

[10] U.S. Patent 6,129,893, Issued October, 2000.

1. Approval of pre-existing data for bin determination, and
2. Approval of defined monitoring sample plan and schedule.

Given the expectations described in the proposal, AWWA is uncertain how many utilities will pursue grandfathering data. In particular, AWWA is concerned about the rigidity with which QA/QC will be treated during the review and especially the expectation for no breaks in sequence of 24 or 48 samples submitted. These two requirements pose tremendous conflicts. Strict adherence to QA/QC criteria is certain to lead to breaks in a continuous sequence of evenly spaced samples and these must be expected. AWWA has encouraged member utilities to pursue grandfathering pre-existing data and/or prepare for the initiation of monitoring under the LT2ESWTR defined monitoring provisions. However, given the volume of guidance associated with this proposal and the issues that need additional consideration by the agency, AWWA questions the feasibility of meeting the proposed deadlines for submittal of pre-existing data for approval (two months after promulgation) or sampling plans (three months after promulgation). Submittal of sampling plans appears to be a particular problem because developing the sample schedule will involve contract negotiation with the laboratory, plus completion of a procurement of services agreement using typical municipal procurement procedures, and all of this occurring between rule promulgation and submittal of the sample plan.

The agency has communicated its perspectives and priorities in the text of the proposal. Given these considerations, AWWA recommends that primacy agency approval of the monitoring plan and schedule should take place prior to initiation of defined monitoring. Utilities have a much stronger and more detailed rapport with state primacy agencies than with EPA regional offices and EPA headquarters. Consequently, interaction with the state rather than EPA regions or EPA headquarters in Washington would be more efficient and effective than the other available options.

4 Specific Provisions

The following are AWWA's comments on specific rule provisions and the basis for those comments.

4.1 "Source" Water Monitoring

In general, the proposed LT2ESWTR rule language reflects the recommendations provided by the Stage 2 M/DBP FACA. In particular, the FACA recommended:

1. Source water characterization is a key first step in the LT2ESWTR regulatory structure,
2. Both defined monitoring and previously collected *Cryptosporidium* oocyst data are appropriate for binning,
3. Twenty-four months are a practical monitoring period on which to base bin determination,
4. Monitoring to employ EPA Method 1622 or EPA Method 1623, and
5. Development of QA/QC procedures for *Cryptosporidium* sampling.

EPA has reflected each of these components in the proposed rule. AWWA continues to believe that each of these five recommendations is sound and appropriate for the LT2ESWTR. AWWA is concerned about the specifics of EPA's implementation of these general recommendations.

4.1.1 Monitoring Location

EPA proposed that "source water monitoring" take place after pre-treatment unit operations, such as off-stream storage, pre-sedimentation, and bank filtration, but before chemical addition (§141.704(b),(c),(d)). The agency also recognized that individual water treatment plants either (1) withdraw water from multiple sources at different times of the year or (2) withdraw water from multiple sources in various blends over the course of the year (§141.704(e)). Utilities with multiple sources may or may not have pre-treatment unit operations. Source water monitoring is perhaps better called plant influent water characterization.

AWWA has contacted most of the commercial laboratories experienced in handling *Cryptosporidium* oocyst samples regarding compositing of *Cryptosporidium* oocyst samples (e.g., §141.704(2)). Their advice was that such compositing can be problematic to undertake and consequently should be avoided if alternative approaches are available. Additionally, the agency recognizes that some PWSs that will have to monitor under the LT2ESWTR only operate a particular water treatment plant for a portion of the year. Consequently, EPA's implementation the FACA's recommendation on "source water monitoring" has become much more complicated than it needs to be. AWWA recommends that EPA change the proposal in the following ways:

1. Change the nomenclature used from "source water monitoring" to "influent water characterization".

2. Define influent water as the water that enters the conventional treatment train or, when alternative treatment technologies (i.e., membranes) are employed, a similar point as established by the primacy agency. Section 141.704(a) provides that

except as otherwise specified in the rule, utilities should sample prior to "any treatment." with the example given as chemical addition at an intake. EPA must more fully describe what constitutes "any treatment." In order to comply with the Stage 1 DBPR, IESWTR, and achieve other treatment objectives, a significant number of utilities add chemicals at the intake and at various points between the intake and the conventional treatment train. Additions may include chemicals such as chlorine, potassium permanganate, cationic polymer, acids, PAC, and lime. Typically, the doses used are small and are not of a nature that available research suggests would significantly affect *Cryptosporidium* oocysts. The addition of a coagulant is commonly added prior to pre-sedimentation. Such addition should not preclude sampling after pre-sedimentation. Any residual coagulant would be minimal and should not affect analytical results. AWWA recommends that "any" be removed from §141.704(a) and that in guidance the agency provide examples of levels of chemical addition or other actions that constitute "treatment" in this context and that would alter the source water monitoring location. Also, the monitoring plan submitted to the primacy agency for approval should include a schematic of the water treatment plant treatment train and indicate where and what chemical additions take place, in particular, additions or actions that take place prior to the proposed LT2ESWTR monitoring location. For utilities that have planned alterations to treatment that impact influent water quality, allow monitoring at a point that reflects the influent water quality following the improvements.

3. Some PWSs that will have to monitor under the LT2ESWTR only operate a particular water treatment plant for a portion of the year (e.g., a utility that operates a plant as a summer peaking supply). The rule should be specific about the monitoring requirements for plants that operate part of a year. AWWA recommends that defined monitoring entail a minimum of 12 samples a year for two years distributed evenly over the time period that the plant operates. If more than 24 samples are taken, they should be evenly distributed.
4. Modify the compliance schedule to incorporate review and approval of the LT2ESWTR monitoring plan by the primacy agency prior to initiation of the required monitoring described in (§141.701(e)).

These recommendations are in keeping with the FACA's direction in that the FACA recommended that a water treatment plant provide increased treatment when the influent water it treated on average (either maximum rolling annual average or arithmetic average) contained elevated levels of *Cryptosporidium* oocysts above certain levels. This proposed approach achieves this goal while providing clear logic for subsequent guidance and primacy agency decisions.

Flexibility in selecting a monitoring location and primacy agency approval of the monitoring plan prior to initiation of monitoring is essential for several reasons. At some water treatment plants, monitoring locations can be physically constrained (i.e., sources may merge in buried facilities or within unit operations). In some circumstances, use of, and blending of, multiple sources is complex and dependant on conditions as they arise on an hourly basis (e.g., changes in demand, withdrawal permit or purchase agreement conditions, and changes in source water quality). Individual utilities will be best able to decide whether monitoring before or after a pre-treatment process is most representative of their source water.

The monitoring location is also of concern to utilities that will grandfather data. The current regulatory language and guidance would preclude submittal of raw water samples drawn from a water treatment plant's source (i.e., river, lake, reservoir, well from which the plant draws water) if one of the pre-treatment toolbox technologies is in place at the plant.[11,12] Based on this regulatory language and guidance, some utilities that continued to monitor at its Information Collection Rule (ICR) monitoring site using EPA Method 1623 would be unable to grandfather its data. Even though such utilities are acting proactively and taking action well beyond regulatory requirements, this potentially grandfathered data would be lost due to the overly restrictive requirements on monitoring location.

4.1.2 Sample Schedule

The approach to sample scheduling outlined in proposal fact sheet is sound assuming the Office of General Counsel (OGC), the Office of Enforcement and Compliance Assistance (OECA), and state primacy agencies understand the deliberate openness in the way the requirements are written.

Breaks in Sequence

While not explicitly stated in the rule language, EPA is interpreting any missing samples within the defined 24-month monitoring period (§ 141.701) or in 24-month monitoring period of previously collected data (§141.708) as a break-in sequence that requires restarting the 24-month monitoring period. This provision, in combination with the agency's lack of a determination of adequate laboratory capacity to undertake the rule and the limited nature of re-sampling provisions in the rule ((§ 141.703(c)), and §141.709(e) described above, result in a situation where utilities making good-faith efforts to comply will be subject to penalty, potentially even punitive placement in Bin 4.

AWWA is very concerned about the agency's current interpretation that the 24-month sampling period must be an unbroken record of samples. This requirement is without basis in the Agreement in Principle or implementation logistics. Moreover, such a provision hinders rather than advances implementation.

As currently written, §141.703(c)-(d) limits when utilities may take replacement samples to two situations:

> (c) If extreme conditions or situations exist that may pose danger to the sample collector, or which are unforeseen or cannot be avoided and which cause the system to be unable to sample in the required time frame, …
>
> (d) Systems that are unable to report a valid *Cryptosporidium* analytical result for a scheduled sampling date due to failure to comply with the analytical method requirements, including the quality control requirements in § 141.705 …[13]

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[11] §141.708(b)(4), 68 FR 47780
[12] Section 2.1.1., Source Water Monitoring Guidance Manual for Public Water Systems for the Long Term 2 Enhanced Surface Water Treatment Rule, June 2003 Draft
[13] LT2ESWTR, Proposed Rule, 68 FR 47778

A conservative interpretation of these provisions would not allow a replacement sample under the following example conditions:

1. Sample processing failure,
2. Laboratory backlog,
3. Sample equipment or material failure (e.g., blown filter, inadequate stock of filters for sampling conditions, etc.),
4. Failure by personnel to follow standard operating procedures for sampling,
5. Improper addressing of a sample so it does not reach a laboratory,
6. Express service failure to deliver sample to laboratory,
7. Labor stoppage that impedes delivery of sample to laboratory,
8. Transport company refusal to ship, or
9. Receiving laboratory exceeds handling capacity, loses approval, or ceases to operate.

Many of these situations impeded sampling in the ICR and could reoccur during the LT2ESWTR monitoring. A creative interpretation of §141.703(d) may provide a basis for the Agency to allow re-sampling, but explicit regulatory language or guidance is needed to provide utilities assurance that the primacy agency staff overseeing data submittal will allow the latitude intended in these provisions.

AWWA has good reason to believe that the above examples represent fact and not conjecture. As stated earlier, the problems listed above reflect utility and laboratory experiences during implementation of the ICR and recent experience of utilities shipping samples in anticipation of grandfathering LT2ESWTR occurrence data. One story relayed to AWWA described a laboratory that had to reject three subsequent sample shipments from a single utility attempting to meet the EPA Method 1623 QA/QC criteria alone. One shipment failed temperature criteria on arrival at laboratory, a second shipment broke open during transport, and a third sample was delivered at temperature (a QA/QC criteria that was arbitrarily selected in development of the method) but did not weigh in at the required volume (e.g., not 10 L but almost 10 L). Laboratories describe a range of success in timely sample transport alone – experiences range from less than 10 to more than 20 percent of large volume samples failing to arrive, arriving late, or arriving damaged. EPA's own experience preparing and distributing Performance Evaluation (PE) samples mirrors the types of experiences described above. These events and other similar mishaps are a reasonable expectation given the tremendous number of samples that will be shipped under the LT2ESWTR. Unfortunately, when the rule is implemented, utilities have a legitimate concern that such stories sound like excuses and, given the workload facing primacy agencies, such stories will not be accepted as fact but discounted and re-sampling opportunities lost.

AWWA is especially concerned at the prospect of limited opportunities to re-sample when the agency is proposing that any failure to monitor per the provisions of the rule is justification to assign that water treatment facility to Bin 4, and then impose the associated treatment requirements.

Alternative Approaches

AWWA recommends four changes to the proposal with respect to missed samples:

1. Expansion of the sample monitoring plans to include "extra" sample events,
2. Additional provision to take replacement samples at the end of the defined monitoring period,
3. Greater flexibility in handling of missed samples when a utility collected 48 or more samples, and
4. Greater flexibility in handling of missed samples in pre-existing data.

AWWA recommends that the monitoring plans submitted to the primacy agency under §141.703(a) include three to six identified monitoring events that could be used to compensate for missed samples not addressed through the re-sample provisions of §141.703(4)(c). These sample events would only be utilized if re-sampling were either not applicable or failed to occur.

AWWA recommends that during monitoring under §141.701(e) utilities should be able to take make-up sample(s) not only immediately after scheduled sample events fail per §141.703(c)-(d) but also at the end of the 24 month sampling period should there be a gap in scheduled sampling. This recommendation is independent of the previous recommendation regarding sample plans, but can be integrated with that recommendation to advance a more comprehensive solution.

Additional samples would be subject to all the QA/QC and frequency requirements of any other sample taken under §141.701(e). EPA's own research illustrates that randomized sampling is equivalent if not superior to time-series sampling designs.[14] These recommendations simply build on the current sampling approach recommended by the Stage 2 M/DBP FACA and would be consistent with the statistical premise for the current monitoring framework. The proposal also limits the monitoring timeframe by the due date for submittal of the monitoring data to the primacy agency for bin assignment. The primacy agency then has the opportunity to make a bin determination based on the available data or to enter into an action plan with the PWS on how it will come into compliance with the LT2ESWTR provisions.

When utilities pursue a more extensive monitoring effort to obtain 48 or more samples, the likelihood increases that sample sequence regularity will be broken. These utilities are making a greater investment in obtaining samples, and they will have a more substantial pool of samples from which to characterize the influent water. Consequently, these utilities should have greater flexibility in handling missing samples in the planned monitoring plan. In addition to having the ability to take additional samples at the end of the defined monitoring period, these utilities should be able to calculate their bin placement based on the arithmetic mean using 48 or more available observations where the sampling sequence was discontinuous in a limited number of instances.

[14] Frey MM and Rosen JS, A framework for modeling the fate and transport of *Giardia* and *Cryptosporidium* in Surface Waters, 1998

Moreover, when evaluating pre-existing oocyst occurrence data, gaps in sequence are likely to occur. Utilities monitoring on a good faith, proactive basis are unlikely to view rapid re-sampling to be a critical aspect of the ongoing monitoring. Utilities engaged in developing *Cryptosporidium* occurrence data in advance of the rule are not only being proactive on behalf of their customers; these utilities are providing the sample workload to maintain the existing baseline level EPA Method 1622/1623 laboratory capacity. AWWA recommends that the agency identify the availability of 48 or more samples as a demonstration of data adequacy that allows more flexible use of pre-existing data with respect to discontinuity in monitoring sequence.

Sample Schedules

Currently, §141.703(a) requires PWSs complying with §141.701(e) to submit a sample schedule in advance of initiating monitoring. AWWA recommends modifying this submittal to also include a schematic with the proposed monitoring location. AWWA also recommends that upon submittal, the primacy agency have a fixed period of time (e.g. three months) to review, approve, and formally inform the PWS that the schedule and monitoring location are approved. Within a fixed period of time (e.g., 60 or 90 days) upon receipt of primacy agency approval, the PWS should initiate monitoring. This review will allow the primacy agency to resolve any conflicts prior to the start of monitoring. A simple and clear appeal process should exist for any issues raised by the primacy agency. Also, the PWS should not be responsible for initiating defined monitoring until the primacy agency has indicated that the monitoring schedule and monitoring location are appropriate.

4.1.3 Grandfathering Provisions

AWWA generally supports the grandfathered data provisions with several outstanding concerns. AWWA believes EPA should address the following concerns:

1. QA/QC requirements for previously collected data almost exclusively limit data submittals to data collected after release of a fact sheet distributed in early 2003 and made available on the EPA web site.
2. Compliance with sample location requirements articulated in the proposal limits data at interested utilities to data collected after June 2003.
3. Compliance with fixed periodicity is unlikely, and large datasets with a continuous, uninterrupted period of record in data collected prior to June 2003 are even more unlikely.
4. AWWA recommends that language be added to Section IV.A.4.d stating: "Failure of EPA to notify the grandfathering plant of its bin determination within four months of promulgation shall delay the required sampling for that plant until two months after receipt of EPA's notification of the plant of the acceptance or non-acceptance of the grandfathered data." The two months will allow the utility to challenge the rejection of the data and / or develop the required sampling plan for the new sampling.

The provisions of the proposed rule have effectively truncated the pool of available preexisting data from data collected after January 1999 to data collected after June 2003, a period of 54 months.[15] More importantly, the rigidity projected in the rule language and guidance creates a disincentive for utilities to collect data until there is a primacy agency to approve their sampling approach and approve re-sampling events. AWWA will not assert that EPA's handling of grandfathered data is contrary to the Agreement in Principle, as the agreement clearly contains grandfathering provisions. However, the agency is not proposing a rule that meets the intent of the Agreement in Principle, as the agency is not:

1. Rewarding utilities that are engaged in proactive source water monitoring that occurred prior to the FACA Agreement (September 2000) or
2. Developing increased lab capacity by encouraging additional monitoring prior to LT2ESWTR implementation.

The previous comments above provide a possible solution for the presence of gaps in a preexisting sample data set. EPA's Source Water Monitoring Guidance Manual for Public Water Systems for the LT2ESWTR provides a useful summary of the agency's expectations for preexisting data. Two additional data quality expectations enumerated in this guidance are unnecessary when reviewing preexisting data:

1. Analysis of a matrix spike at least every 20 monitoring samples, and
2. Minimum sub-sampling analysis requirements.[16]

AWWA agrees with proposed guidance that a matrix spike sample that fails QA/QC need not be re-sampled. Moreover, AWWA recommends that the matrix spike sample requirement be struck from the guidance. This requirement is already reflected in the analytical method but not utilized by the LT2ESWTR rule provisions.[17] AWWA also recommends that the minimum sub-sampling analysis be modified to reflect that the laboratory followed prevailing good laboratory practice regarding sub-sampling at the time of the sample's handling. As proposed, matrix spike samples are an excellent practice, but their use will not substantively affect acceptance of LT2ESWTR samples (i.e., failure to process matrix spike is an issue but the sample will not be used to inform the use of the actual monitoring samples).

Minimum sub-sampling analysis is a new component of the last published version of EPA Method 1622/1623. There was not a fixed requirement for this until EPA undertook the recent refinements of the method and emphasized this component. Prior to this version, based on ongoing discussion with the approved protozoan analysis laboratories, sub-sampling occurred based on the professional judgment of the analyst. Informal polling of approved protozoan

[15] A more generous interpretation would be that the 2001 Stakeholder Draft for LT2ESWTR contained enough information to guide practice substantially similar to August 11, 2003 proposal. Were this the case, then December 2001 would have been the earliest possible date for valid data collection and the resulting period would be 35 months

[16] Source Water Monitoring Guidance Manual for Public Water Systems for the Long Term 2 Enhanced Surface Water Treatment Rule, Section 2.1, p. 8.

[17] Guidance on Generation and Submission of Grandfathered *Cryptosporidium* Data for Bin Classification Under the Long Term 2 Enhanced Surface Water Treatment Rule, April 2003, p. 6.

analysis laboratories suggests that less than 10% of Method 1622/1623 samples require sub-sampling per the current method criteria. Consequently, AWWA does not believe that sub-sampling is as significant a concern with EPA Method 1622/1623 as it was for the ICR Method and, moreover, analysts employ sub-sampling when necessary as a matter of good laboratory practice. Therefore, the proposed criterion is unnecessary and should be removed from the grandfathered data QA/QC criteria.

4.1.4 State Role in Bin Placement

The question of the state's role in bin placement is an important one. In fact, EPA poses the question directly in §IV(C)(2)(c).[18] The Stage 2 M/DBP FACA and the agency both recognized in developing the Agreement in Principle and the rule itself that the "bin borders" reflected in §141.709 reflect a high degree of conservatism. Consequently, the placement of individual utilities within individual bins must involve an opportunity for dialogue with the primacy agency. This dialogue should focus on three essential components:

1. The mean *Cryptosporidium* concentration and bin placement derived from the data submitted in the defined monitoring period (§141.701(e)) or grandfathered data (§141.708),
2. The quality of the available data, and
3. Other data available to the utility such as additional monitoring at the required monitoring site.

Each of these components should be factored into the bin determination.

The proposal preamble, regulatory language, and guidance are quite voluminous, but almost silent on the mechanism by which bin determination actually occurs. Coverage of this issue is limited to the bin definitions reflected in §141.709. The proposal contains no discussion on the associated decision making process. One aspect discussed briefly in guidance is the flagging of contested data in the electronic data system for submittal of §141.701(e) monitoring data.[19] This brief discussion does not address the handling of contested data.

AWWA recommends that EPA expand the LT2ESWTR Guidance to reflect an appropriate evaluation process and dialogue between the affected PWS and the primacy agency. This process should include an administrative process for handling of contested monitoring data, and the discussion of additional data developed by the utility.

4.1.5 5.5-Log Treatment Exemption

Utilities that proactively commit to investment in advanced treatment should not be burdened with unnecessary monitoring requirements or administrative procedures. The proposed rule contains provision in §141.701(f) where systems that achieve the level of treatment required by Bin 4 (i.e., 5.5 log credit) may notify the primacy agency in lieu of monitoring for oocysts in

[18] 68 FR 47685
[19] Source Water Monitoring Guidance Manual for Public Water Systems for the Long Term 2 Enhanced Surface Water Treatment Rule, Section 7.2.2., p. 51.

their influent water. This procedure is sound given the other rule requirements and should be retained in the final rule.

4.1.6 Six-Year Review of Bin Boundaries

The Agreement in Principle provides for a second round of monitoring six years after completion of initial bin characterization. This provision is reflected in the proposed rule and described in the preamble to the proposed rule. The preamble also notes that sanitary surveys provide an opportunity to evaluate any change in average oocyst levels and associated changes in the watershed. The Stage 2 M/DBP FACA explicitly provided for stakeholder dialogue to evaluate appropriate analytical methods and associated bin structures. Perspectives on the risk of cryptosporidiosis from drinking water will likely change in the future based on new analytical methods, observations drawn from the initial bin determinations, and health effects research. One example of new research is the Aboytes and LeChevallier paper, which is discussed below. EPA should be extremely careful to allocate sufficient time and resources to agreed-upon discussion with stakeholders prior to the second round of LT2ESWTR monitoring. Additionally, EPA needs to ensure that PWSs are informed with an ample amount of time to react and prepare for initiation of this second round of monitoring. EPA also needs to ensure appropriate funding for microbial and disinfection byproduct research.

Aboytes and LeChevallier, 2003

Aboytes and LeChevallier presented findings from a recent study of 82 surface water treatment plants, which enumerated *Cryptosporidium* oocysts using a combination of techniques including immunomagnetic separation (IMS) to recover oocysts, HCT-8 cell culture to select for viable oocysts, polymerase chain-reaction (PCR) reactions for DNA amplification, and agarose gel electrophoresis as a sensitive detection method for viable, infectious oocysts.[20] This effort represents a useful proof of concept study combining not only the development of analytical techniques, but also illustrating application of the method across a variety of water matrices. In total, more than 1,800 samples were processed. This study has generated significant interest in the drinking water community because its findings are provocative. The findings include:

1. Observed occurrence of oocysts in finished water was independent of observed source water quality,
2. Little apparent relationship between system size, land use, or age of plant and observed oocyst occurrence in finished water,
3. Observed occurrence of oocysts in finished water was independent of observed finished water turbidity.

Each of these observations is at odds with the underlying precepts of the LT2ESWTR proposal. AWWA found these study findings to be interesting and potentially informative. AWWA is recommending that potential funding organizations support conducting a similar, robustly designed study to verify this initial study's findings. AWWA found these results difficult to reconcile with recent epidemiological studies in the U.S. and Australia. These studies have not

[20] Aboytes and LeChevallier, American Water Works Association, Proceedings 2003 Annual Conference, New Orleans, 2003.

demonstrated discernable levels of waterborne disease attributable to drinking water supplies believed to be positive for *Cryptosporidium* (e.g., Melbourne, Australia, and Davenport, Iowa).[21]

Aboytes and LeChevallier illustrates that if EPA and its research partners maintain an active research agenda, potential developments in analytical techniques and the science generally regarding *Cryptosporidium* could change (1) our collective view on the need for a second round of monitoring, (2) the tools and techniques used to undertake future monitoring, and (3) the sampling plan for such future monitoring.

4.1.7 Analytical Methods

EPA Method 1623 As Applied

Improvements to EPA Method 1622/1623 are important and beneficial, but the assumption that method adoption will occur rapidly upon release of method updates is unreasonable. A review of the history of this method's development has been one of fits and starts. Consequently, laboratories and utilities have taken a wait-and-see approach to adoption of method enhancements and have focused on ensuring that lab staff was able to perform a particular approach as well as possible. This reluctance to shift from established practice to an untried variant with unknown reproducibility should not be penalized in LT2ESWTR source water monitoring grandfathering provisions.

Holding Times and Temperature

EPA has, through recent method revisions to EPA Method 1622/1623, revised holding times and proposed revision of required holding period temperatures. The revised holding times are important changes to facilitate processing LT2ESWTR monitoring samples. Likewise, the proposed revision of the 8°C holding temperature to 10°C is an important modification that will facilitate sample management without significantly affecting method performance. AWWA encourages the agency to continue to explore sample holding temperature, as at present there is not any specific data that suggests that higher temperatures would be detrimental to enumeration of presumptive oocysts under LT2ESWTR.

***E.coli* Method Holding Times**

AWWA agrees that the holding time study conducted by EPA, Wisconsin State Laboratory of Hygiene and a number of other participants as reported in Pope *et al*, 2003, provides sufficient information to support longer holding times for *E.coli* source water samples.[22] EPA proposes a holding time of 24 hours for all considered *E. coli* methods. AWWA believes that the 24-hour hold time is appropriate for all of the methods considered in Pope et al. AWWA would further recommend that the hold time for at least the Colilert® method (if not a broader selection of *E. coli* methods) be extended to 36 hours per the demonstration of performance in Pope *et al.* AWWA does not endorse Colilert® itself or its manufacturer, but the study indicates that a longer hold time is possible with Colilert® and there will be utilities for which the 36-hour hold

[21] Margaret E. Hellard, Martha I. Sinclair, Andrew B. Forbes, and Christopher K. Fairley, A Randomized, Blinded, Controlled Trial Investigating the Gastrointestinal Health Effects of Drinking Water Quality, Environ Health Perspect 109:773-778 (2001).

[22] Pope, M., M. Bussen, M. Feige, L. Shadix, S. Gonder, C. Rodgers, Y. Chambers, J. Pulz, K. Miller, K. Connell, and J. Standridge. 2003. Assessment of the effects of holding time and temperature on E. coli densities in surface water samples. Appl. Environ. Micro. (submitted).

time will greatly facilitate sample delivery to a certified compliance laboratory. The additional hold time also will provide utilities in more remote locations some buffer against the need to repeatedly resample due to vagaries of express package delivery.

Specific Requests for Comment from EPA, 68 FR 47685 §IV(C)(2)(c)

The preamble discussion of LT2ESWTR monitoring provisions includes a number of specific requests for comment (68 FR 47678).

Request(s) for Comment

Appropriate monitoring requirements for systems that use surface water for only part of the year and how to apply LT2ESWTR monitoring requirements to surface water systems that operate or use surface water for only part of the year.

Response

Plants that operate only part of the year should take source water samples only during the period of operation. Samples should be taken on a frequency that results in a minimum of 12 samples obtained during the annual period of operation. This will require sampling more frequently than once per month. Samples should be distributed evenly throughout the operational period. The monitoring plan for LT2ESWTR should reflect this compression of 12 samples into the plant operational period. Approval of this monitoring plan by the primacy agency prior to the start of sampling is essential to provide these plants with assurance that their monitoring results will be accepted for compliance purposes.

Request for Comment

Whether or under what conditions previously collected data that do not meet the proposed criteria for LT2ESWTR monitoring data should be accepted for use in bin determination.

Response

EPA began the Protozoan Laboratory Approval Process in 2002. Consequently, grandfathered data falls into three classes:

1. Data collected since a laboratory has been approved by EPA but prior to rule initiation.
2. Data collected by laboratories with EPA Method 1622/1623 prior to being approved by EPA.
3. Data collected by laboratories using methods other than EPA Method 1622/1623 *per se* but demonstrated (with documentation) to be equivalent to that analyzed by laboratories adhering to EPA Method 1622/1623 QA/QC procedures and PT sample performance.

In the proposal, EPA has already addressed the first category of data, but has not addressed the second or third class of data described above. Using data in the second class above would require the laboratory to demonstrate a history of meeting the QA/QC and performance testing criteria indicated in EPA Method 1622/1623 within the limits of accepted practice at the time the samples were taken.

With respect to the third class of data, EPA Method 1622/1623 is a performance-based method. Through a Tier 1 or Tier 2 evaluation, as appropriate under EPA's performance-based methods guidance, individual laboratories can demonstrate equivalent performance and submit data from methods that are not a step-by-step implementation of the EPA Method 1622/1623 procedure. Rather, the method allows for any modification other than the determinative step (i.e., differential interference contrast (DIC) microscopy) that achieves comparable recovery, precision, and accuracy. Inferred from the FACA's recommendations is a requirement for analysis of at least a 10-liter sample, and an average recovery similar to that assumed in the FACA binning algorithm (average of 40%).

The 10-liter sample provision in the LT2ESWTR proposal stems directly from the Stage 2 M/DBP FACA agreement and AWWA supports the provision. However, this criterion does represent a significant limitation on existing data. AWWA suggests that the basis for the 10-liter sample is actually a product of the binning algorithm, which requires 240 L or 480 L of sample volume be collected. One means of accommodating smaller individual sample sizes while remaining consistent with the Agreement in Principle would be allow samples where the total volume of samples were representative across time and, in total, represented 480 L or more of total sample volume.

Request for Comment

Sampling frequency requirement for previously collected data, and whether EPA should allow samples collected at lower or varying frequencies to be used as long as the data are representative of seasonal variation and include the required number of samples. If so, how should EPA determine whether such a data set is unbiased and representative of seasonal variation? How should data collected at varying frequency be averaged?

Response

As noted above, the basic sampling framework recommended by the Stage 2 M/DBP FACA was:

1. Random sample,
2. Minimum period of 24 months,
3. Reward larger data sets (i.e., 48 samples get to use arithmetic average rather than maximum rolling 12-month average),
4. Minimum of 240 L sampled, and
5. Desired average recovery rate of 40%.

Data collected both prior to, and after the rule is finalized, are unlikely to rigidly adhere to a fixed monitoring frequency within the sampling window described in the proposal. The implications of a missed sample point were not apparent from the rule, preamble, or supporting guidance, but rather through verbal communication with EPA staff. The FACA's interest in setting a fixed schedule was to ensure that events that might increase oocyst occurrence were not avoided over the course of the defined monitoring period. The goal of the sampling program must be to obtain sufficient representative source water quality data to allow appropriate placement of the treatment plant into the correct bin. Strict adherence to a schedule as described by EPA is not necessary to achieve the FACA's objective and is unlikely to have been met in older data sets. Consequently, the agency should afford greater flexibility in handling missed sample events and lack of fixed periodicity with increasing number of samples particularly when 48 or more samples have been obtained.

Grandfathered data sets may encompass longer periods of record and are likely to contain gaps in sampling events. Having a longer period of record is desirable and should not cause the data to be unacceptable. Where only 24 samples are available, the algorithm used to determine a treatment bin is the maximum 12-month rolling average in period. Similarly, where 48 samples are available, the arithmetic mean of all of those values should be employed. In the event more than 48 samples are collected, then the samples selected should first be screened for data quality and the most recent 48 values employed to calculate an arithmetic mean. The rationale behind this recommendation is that laboratory practices and analytical techniques are improving over time, so using the most recent data will capture the highest quality data and reward a utility for initiating its monitoring early and maintaining an ongoing monitoring effort.

Request for Comment
Alternative approaches for systems that fail to complete required monitoring, such as classifying the system in a bin based on data the system has collected, or classifying the system in a bin one level higher than the bin indicated by the data the system has collected.

Response
This topic is discussed in detail in Section 4.1.2 above. Under no circumstances should the final LT2ESWTR include punitive provisions that force a utility to take on a higher level of treatment than is needed based on documented occurrence of *Cryptosporidium* oocysts in the influent water to the facility.

Request for Comment
Monitoring and treatment requirements for new plants and sources.

Response
New facilities should conduct 24 months of monitoring employing EPA Method 1622/1623 for *Cryptosporidium* oocysts. As with existing facilities, new facilities should be afforded the opportunity to take 24 or 48 samples and average accordingly. Each primacy agency should identify in its permitting guidance when in the design process the information must be submitted to the primacy agency. New water treatment facilities should be designed based on the log credit system reflected in the microbial toolbox and inactivation provisions identified in LT2ESWTR.

Request for Comment
How the effect of recycling filter backwash should be considered in LT2ESWTR monitoring.

Response
The Filter Backwash Recycle Rule (FBRR) regulates allowable recycle practices at treatment plants. The intent of the FBRR is to encourage implementation of recycle practices that do not negatively impact performance of a treatment plant. In other words, facilities operated using practices consistent with the FBRR should achieve equivalent, or superior performance to the same facility operated without recycle. Consequently, other regulations do not need to

incorporate provisions for recycling because all consequences of recycling practices are accounted for in systems complying with the FBRR.

Cornwell and MacPhee 2001, Cornwell et al. 2001, and Nieminski and Bellamy 2000 provide data supporting the contention that recycle practices consistent with FBRR do not negatively impact performance of clarification systems, or the combined performance of a clarification plus filtration system. Cornwell et al. and Cornwell and MacPhee reported results from pilot studies involving impact of SFBW recycle on a system with clarification (plate settler) followed by a dual media filter.[23,24,25] Aerobic spore and *Cryptosporidium* data from these published papers is summarized and analyzed in Appendix 1. AWWA concludes from this analysis and our previous experience reviewing the Filter Backwash Recycle Rule (FBRR) that recycle issues are adequately addressed in context of FBRR and should not be part of LT2ESWTR.

4.2 Toolbox Components

Both AWWA and EPA have undertaken detailed reviews of the available literature and observations from utility operations. EPA indicates repeatedly in the LT2ESWTR preamble an interest in the objective review of the data presented in the preamble and for new information. AWWA's careful review of data from the available literature and full-scale and pilot-scale data from U.S. drinking water utilities substantiate meaningful log-credits for conventional clarification and filtration, direct filtration, and for the following toolbox components:

1. Off-stream raw water storage,
2. Pre-sedimentation,
3. Lime softening (single- and two-stage),
4. Improved filtration (combined filter effluent turbidity <0.15 NTU, 95 percent of the time),
5. Multiple filtration processes (separate serial filtration stages), and
6. Slow sand filtration.

A detailed review of the available data is included in Appendix 1 and Appendix 2 to these comments. Appendix 2 was provided to EPA in January 2001 in response to the stakeholder draft of the LT2ESWTR and Appendix 1 reflects both additional data and analysis specifically directed to issues posed by the LT2ESWTR proposal. The following is a brief summary of observations from the analyses in Appendix 2:

1. Conventional dual-media or mono-media filtration following clarification treatment are capable of demonstrating 4.0 log or greater removal, often 5.0 log or greater,

[23] Cornwell, D., M. MacPhee, N. McTigue, H. Arora, G. DiGiovanni, and J. Taylor. 2000. Treatment Options for Giardia, Cryptosporidium, and Other Contaminants in Recycled Backwash Water. Denver, CO: AWWARF and AWWA.
[24] Cornwell, D. and M. MacPhee. 2001. Effects of Spent Filter Backwash Recycle on Cryptosporidium Removal. JAWWA. 93(4):153-162
[25] Nieminski, E. and W. Bellamy. 2000. Application of Surrogate Measures to Improve Treatment Plant Performance. Denver, CO: AWWARF and AWWA.

and typically demonstrated greater removal than the 3.0 log baseline *Cryptosporidium* log credit in the LT2ESWTR toolbox. Therefore, some toolbox credit is needed to correct or adjust the assumed median 3.0 log performance upward to the actual 4.0 log or higher removal at which many facilities routinely operate.

2. Clarification technologies suitable for the 3.0-log *Cryptosporidium* baseline credit, if followed by a conventional dual-media or mono-media filter operating in compliance with the Interim Enhanced Surface Water Treatment Rule (IESWTR), include: gravity sedimentation basins, tube settlers, plate settlers, sand-ballasted coagulation, dissolved air flotation (DAF), upflow solids contact reactor-clarifiers, or buoyant or non-buoyant media upflow clarifiers.
3. No indicators have yet been identified that accurately reflect occurrence of *Cryptosporidium* in either raw or finished water.
4. Numerous pilot and spiking studies indicate that total aerobic spores, as well as *Bacillus subtilis* spores (a subset of total aerobic spores), are a reliable conservative indicator of *Cryptosporidium* removal using clarification and filtration technologies typically employed for drinking water treatment, as long as water is properly coagulated.
5. 0.5 log *Cryptosporidium* credit for 21-day off-stream raw water storage and 1.0 log for >60 day storage are indicated from currently available literature data. Log credit for off-stream storage is appropriate not only because of *Cryptosporidium* removal, but also due to microbial antagonism (predators and competitors) and natural die off. Monitoring after off-stream raw water storage will most readily reflect this removal.
6. Continuously operated pre-sedimentation basins are suitable for a credit of at least 0.5 log.
7. Single-stage lime softening, i.e., a single clarification stage followed by conventional filtration, is suitable for at least a 3.0 log baseline credit, identical to the credit assigned to other combined clarification plus filtration technologies.
8. Two-stage lime softening (a second clarification stage added to single-stage softening) is suitable for a total *Cryptosporidium* removal credit of at least 3.5 log, consistent with a 0.5 log toolbox credit added for the second clarification stage.
9. Two-stage lime softening preceded by a pre-sedimentation basin provides at least 4.0 log *Cryptosporidium* removal, consistent with a 0.5 log credit for pre-sedimentation and a 0.5 log credit for the second clarification stage.
10. Log removals cited for lime softening are not dependent upon addition of a coagulant, such as organic polymer or a metal salt
11. Available information indicates that achieving a 0.15-NTU combined filtered water turbidity (CFE) achieves more than 1.5-log greater *Cryptosporidium* removal than a facility achieving 0.30 NTU in CFE.

12. Two filtration stages operated in series are capable of providing more than 0.5-log additional *Cryptosporidium* removal above the level capable of being achieved by either of these filters acting alone.
13. Slow sand filtration, when operated as outlined in the Surface Water Treatment Rule (SWTR), is capable of achieving a 3.0-log baseline *Cryptosporidium* removal credit as a stand alone system, or a >2.5-log credit as an add-on toolbox component.
14. Available studies demonstrate that recycle of spent filter backwash water, using acceptable practices consistent with the Filter Backwash Recycle Rule, will not deteriorate *Cryptosporidium* removal during conventional clarification plus filtration technologies, nor should it deteriorate log credits assigned for individual toolbox components.

This analysis and these findings provide an important factual basis for the recommendations AWWA offers in the following comments. AWWA's review includes both research and data identified in the LT2ESWTR proposal. AWWA believes the analysis in Appendix 1 and reflected in these comments more correctly reflects the performance of some of these treatment technologies than the discussion provided in the Federal Register notice and Microbial Toolbox Guidance. In addition to the literature and analysis presented in Appendix 1 and Appendix 2, AWWA will also provide information and analysis with respect to watershed control programs, bank filtration, ozone disinfection and UV disinfection.

4.2.1 Regulatory "Preference" vs. Agreement in Principle

Before, during, and after the FACA negotiations, EPA has favored particular tools within the microbial toolbox, especially inactivation (UV) and, in two instances, removal (i.e., combined filter effluent, and membranes) over others. The proposed rule and associated guidance manuals reflect this favoritism, particularly in the definitions and requirements assigned to other toolbox alternatives. Where the agency does not eliminate the toolbox element, the following severe constraints make most of the toolbox technologies unattainable:

1. EPA has defined requirements for credits that are unachievable at most facilities that will need the credits, particularly with respect to individual filter effluent and new pre-sedimentation basins turbidity requirements.
2. EPA has included provisions that make toolbox alternatives unattractive to utilities that might otherwise choose them (i.e., demonstration of performance (DOP) and watershed control program (WCP)).
3. EPA provided misleading information that discourages utilities from using or even investigating some toolbox alternatives.

The following section reviews each of the toolbox elements and provides a number of recommendations for improvement of the proposed rule and associated guidance.

The proposed rule and guidance manuals either include unrealistic requirements for some of the credits or do not include adequate assurance to utilities that a credit will be sustainable for the utility (e.g., see WCP discussion). If a utility cannot reliably depend on a credit, it will have to choose other credits types it believes will be available. A credit that a utility cannot depend upon is not really a credit. As proposed, the Microbial Tool includes several tools that are credits in name only. If the proposal remains unchanged when it is promulgated as a final rule, facilities in Bin 2 will essentially only have membranes and inactivation as compliance alternatives. Though the CFE credit will also probably be available, it is only worth 0.5 credits so additional credits via inactivation or membranes will still be needed if no other 0.5 credit options are realistically available.

Given the much higher cost of membranes, with the possible exception of bag and cartridge filters for small systems, UV will be only practical means of compliance. Although UV inactivation has enormous potential benefit for the water treatment industry, reliance on a single technology is potentially prone to error if any future difficulties develop with the respect to UV disinfection. This is inconsistent with the Stage 2 M/DBP Agreement in Principle. The capital cost for UV is relatively inexpensive in comparison to other toolbox technologies, but the operation and maintenance cost could be significant, and is not well defined by industry experience.

In order for the microbial toolbox concept to work as originally intended, to provide a variety of alternatives, and to allow establishment of credit that existing facilities already deserve:

1. Several of the requirements for some of the credits needs to be refined, and
2. Additional information needs to be provided to more objectively present the benefits of some of the toolbox alternatives to utilities that might use them.

In particular, while some facilities with two-stage filtration or clarification may get some benefit from these specific credits, and some systems with existing BF or pre-sedimentation may get an indirect benefit because they will be collecting *Cryptosporidium* bin assignment samples from the end of these processes, the four toolbox alternatives that will probably have the most widespread use are CFE, IFE, DOP, and WCP. If these are properly defined, many utilities will be able to use existing facilities to meet requirements for Bin 2, or they can add 0.5 credit with WCP if they need the additional credit or if they want an additional 0.5 credit safety factor. Even though utilities in Bin 3 or 4 can use inactivation and membrane alternatives to meet all of their treatment requirements, utilities should be encouraged to use CFE, IFE, DOP, or WCP. CFE, IFE, DOP, and WCP are ongoing performance based measures that enhance existing barriers in a multiple-barrier treatment strategy.

WCP, IFE, CFE, and DOP credits should be encouraged because these microbial toolbox components have far-reaching positive benefits for *Cryptosporidium* protection. For example, a realistically defined IFE credit will not mean the credit will be easy to achieve. Careful management and operational practices from source water through all stages of treatment will be required for this credit. Encouraging improved performance, and rewarding facilities that already achieve a suitably high level of performance, meets LT2ESWTR objectives and promotes well-designed and well-managed drinking water treatment facilities. Many forward-thinking utilities will strive to achieve this level of performance without needing the additional motivation of the IFE credit. Still, AWWA recommends that EPA include a more realistic definition of the IFE credit (see section 4.2.6) in order to encourage more utilities to try to improve performance to meet the credit. The IFE credit as currently defined is so prohibitive that utilities are unlikely to even attempt meeting its requirements. Consequently, an important incentive for utilities to improve filtration performance has been lost.

The WCP credit is another toolbox alternative that can have far-reaching and long-lasting benefits for facilities that perform WCP related activities. However, the WCP credit as currently defined provides little, if any, motivation for utilities to attempt to achieve this credit. Facilities that might have tried for a more realistically defined credit will not gain the broad benefits which WCP related activities could provide (see section 4.2.2).

As the WCP, DOP, and IFE provisions are currently described, they do not properly credit the *Cryptosporidium* protection achieved at existing utilities. Moreover, they represent a missed opportunity to encourage practices and programs that have potential long-term benefits as barriers not only for *Cryptosporidium* but also for other contaminants that may be identified in the future. The treatment alternatives encouraged by the proposed rule rely on high cost, technology intensive treatment processes that are inserted into existing treatment processes. This dependency on add-on, single purpose, disinfection technologies runs counter to the known benefits of multi-barrier approaches to treatment. AWWA's comments include important changes to the proposed microbial toolbox that EPA should incorporate so that the agency, utilities, and the public may obtain the benefits anticipated under the toolbox framework as structured by the Stage 2 M/DBP FACA.

4.2.2 Watershed Control Program

AWWA believes that, as currently formulated, the Watershed Control Program (WCP) is not a viable LT2ESWTR toolbox element. Key aspects of the WCP regulatory provisions and guidance are inconsistent with the intent of the Agreement in Principle. We are extremely concerned that the draft guidance creates disincentives for utilities with good potential for implementing source water protection for regulatory credit, and that utilities currently engaged in source water protection are penalized rather than rewarded for their proactive effort.

In our view, the agency's proposed approach includes the following critical flaws:

1. Unjustified requirements which interfere with the core mission of a source water protection program and this interference escalates with every "re-approval cycle" (sanitary surveys, monitoring, etc.)
2. Existing watershed control programs and source water protection efforts are not credited
3. Lack of integration with Clean Water Act (CWA) watershed restoration programs including failure to recognize the time scale for CWA-related actions
4. No acknowledgement it may take more than a decade to realize measurable improvements in water quality after initiating watershed restoration efforts
5. Implication that reductions in *Cryptosporidium* oocyst levels at drinking water intakes are expected within the six-year timeframe prior to a second round of defined monitoring

Our concerns and recommendations are discussed in more detail below:

§141.730 Re-approval (FR 47791 Microbial Toolbox Reporting Requirements)
Re-approval of a WCP every six years was not part of the Agreement in Principle. This requirement places a greater burden on the WCP than on treatment-based toolbox items. As written, the six-year re-approval process for the WCP creates an upward spiral of requirements for utilities engaged in source water protection efforts. This conflicts with the agency's general approach to source water protection, which is based on steady incremental progress on a watershed basis.

In crafting the microbial toolbox, the Stage 2 MDBP FACA expected that the WCP would be widely utilized and thereby provide long-term and wide-reaching public health benefits (though not necessarily immediately measurable) to the nation. However, because of the huge uncertainty associated with the six-year re-approval process outlined in the proposed guidance, even utilities at the forefront of watershed control in the United States have indicated they could not plan to utilize this credit with confidence. This lack of confidence indicates that the intent of the Agreement in Principle with respect to WCP toolbox credit has not been met.

The AWWA recommends that EPA eliminate the re-approval requirement from the regulation and remove associated references from guidance (LT2ESWTR Toolbox Guidance Manual). The WCP should be designed such that, once initially approved, systems meeting the WCP requirements retain their approval status. Primacy agencies certainly need a way to monitor utilities' progress under WCPs. This could be fulfilled by submission of an annual or triennial report describing the utility's ongoing WCP activities and programs. The primacy agency could use such a reporting tool to determine whether a system is engaged in an active WCP program, given the size and resources of the utility. The reports would also provide a basis for discussion of the WCP plan during regular sanitary surveys. If a utility failed to demonstrate adequate commitment to their WCP, the primacy agency could deny them eligibility for the 0.5 log toolbox credit until they obtained WCP re-approval. Examples of appropriate report elements include:

1. WCP milestones achieved in the reporting period,
2. Metrics of pertinent activities during that reporting period (e.g. miles of stream bank fenced, acres of buffer purchased, etc.),
3. Summary of outreach activities conducted in that period,
4. Program budget, and
5. Summary of assigned personnel.

Existing Programs Need Fair Credit (Toolbox Guidance Manual §2.2.3 p.2-6)
The guidance indicates that existing WCP efforts do not count towards WCP approval under LT2ESWTR:

> "Systems that already have a watershed control program in place are permitted to choose this option; however, they will have to amend and strengthen their programs to get the log removal credit. … To get the additional credit, a system with an existing

watershed control program could, for example, increase public outreach efforts or toughen land use ordinances that affect water quality."

Setting a higher bar for existing efforts and relative to new efforts is arbitrarily punitive toward established programs. The agency should remove this distinction from guidance for this toolbox element to become a meaningful and realistic tool for LT2ESWTR compliance.

The agency must recognize and acknowledge that the efforts and effects of existing source water protection programs may not be evident or manifest at the time of initial WCP application but may require extended time periods (i.e., years or decades) to become observed. Progress made by such programs prior to the LT2ESWTR should not be considered on any less than an equal footing with new efforts spurred by the regulation. Primacy agencies should not be incited to suggest changes to existing source water protection programs during evaluation for WCP credit under LT2ESWTR, solely for the sake of noting a change on paper. Such changes could counteract years of groundwork, relationship-building, and resource investment by a utility and its partners that could have yielded significant improvements down the road if left unaltered.

The AWWA recommends that source water protection activities and implementation efforts by utilities prior to initial WCP approval be included in the program evaluation. Existing source water protection activities of significant value to the WCP process should not be altered or adjusted in order to show something new. Nor should existing programs be directed to "start from scratch" in order to fit a "model" WCP approach articulated in guidance or envisioned by a primacy agency.

§141.725(a)(4)(ii) Annual Watershed Sanitary Survey

The requirement to report results of an annual watershed sanitary survey conducted by persons approved by the primacy agency imposes a substantial additional burden on utilities' resources without any supported benefit. As such, the lack of benefit detracts from the viability of the WCP toolbox element and thereby conflicts with the intent of the Agreement in Principle to encourage source water protection efforts. Though not stated explicitly, in addition to fiscal and reporting burdens, watershed sanitary surveys imply monitoring requirements.

Current primacy agency efforts to implement watershed restoration and develop Total Maximum Daily Loads (TMDLs) for contaminants such as nutrients and sediment take at least a decade to achieve measurable results. The TMDLs for these contaminants are supported with substantial field data and significant technical basis in the literature. Through the CWA, such restoration programs have regulatory authority and resources at their disposal. To expect that a water utility's WCP can address a much more complex contaminant in a shorter period of time and without regulatory authority is unrealistic and contrary to the agency's programmatic approach on watershed-based decision-making. The AWWA believes that in order for the LT2ESWTR WCP toolbox element to spur real improvements in our nation's source waters with efficient use of resources the agency must acknowledge the long-term nature of watershed protection efforts. These efforts should be viewed on a decade-order rather than annual time scale. The agency must neither expect nor require observable reductions of *Cryptosporidium* at affected water treatment plant intakes as proof of the benefit of these programs.

The proposal and guidance do not provide a rationale for additional watershed surveys on an annual or any other frequency basis. The expectation for annual surveys contrasts sharply with the extended time schedules EPA and states apply to stream assessments for Clean Water Act (CWA) impairments. Furthermore, the agency encourages primacy agencies to conduct CWA Section 305 watershed reviews on a rolling schedule, wherein individual watersheds are evaluated on a much longer timeline than the three-year schedule set in the CWA. Extended timelines under CWA are intended to ensure productive use of resources by allowing adequate evaluation of a watershed when its review occurs and providing a timeframe over which demonstrable change could be observed.

If the goal of the survey is to use water quality monitoring to detect improvements in water quality at the watershed level, an annual monitoring regime is not an effective use of resources. Watershed restoration studies typically yield significant discernable water quality improvements at the watershed level over decades after mitigation activities have begun (in streams that aren't first order). Acquiring the necessary background information to support a routine survey effort is a significant effort and has many practical constraints. In most areas, state and federal agencies collect land-use information, discharger information, agricultural and population census, as well as pertinent watershed characteristics. This information is not updated on an annual cycle. Periodicity of such data collection efforts ranges from annual to decennial. Implementing a watershed sanitary survey program at less than a 10-year frequency is unlikely to provide additional value to the WCP approach and will likely detract resources away from key program activities such as source tracking and identification, partnership development, and best management practice design and implementation.

The AWWA recommends that the agency either remove the WCP watershed sanitary survey provision from the proposed rule and associated guidance or else revise it to be commensurate with comparable watershed programs under CWA authority. Employing comparable timeframes will provide synergy to facilitate watershed-based efforts falling under the different regulatory programs and thereby promote needed integration between SDWA and CWA statutes.

Specific Requests for Comment from EPA, 68 FR 47685 §IV(C)(2)(c)

EPA requests comment on the following specific topics regarding watershed control programs in context of microbial toolbox.

Request for Comment

Should the state be allowed to reduce the frequency of the annual watershed survey requirement for certain systems if the systems engage in alternative activities such as public outreach?

Response

As noted above, the AWWA recommends that EPA strike this provision from the LT2ESWTR. In no case should the frequency of a watershed sanitary survey associated with a WCP toolbox credit be shorter than 10 years. The primacy agency should be allowed to reduce the frequency of annual watershed survey requirements based on local circumstances regardless of whether the system is specifically engaged in public outreach.

This request for comment is complicated by the lack of definition for "public outreach." Based on the AWWA's experience, the relevant questions are: (1) On what frequencies would such surveys contribute to the effectiveness of a WCP? And (2) at what frequencies can observable change be expected? Whether the utility has held a public meeting, organized a stakeholder committee, or held watershed events at local schools is not directly pertinent to these questions.

Request for Comment
The effectiveness of a watershed control program may be difficult to assess because of uncertainty in the efficacy of control measures under site-specific conditions. In order to provide constructive guidance, EPA welcomes reports on scientific case studies and research that evaluated methods for reducing *Cryptosporidium* contamination of source waters.

Response
A number of studies currently ongoing and recently published indicate the effectiveness of various best management practices (BMPs; structural and non-structural) at reducing *Cryptosporidium* loadings to waterways. Appendix 3 provides a summary of some of the relevant published literature on the effectiveness of BMPs. Most studies have focused on the effectiveness of riparian buffers or grass filter strips in agricultural areas to reduce loadings from animal runoff. One recent study has documented greater than 3-log reduction of oocysts by riparian buffers (Atwill et al. 2002). New studies on enhanced removal of dissolved phosphorus by amending riparian buffers with water treatment residuals may also indicate benefits for enhanced removal by filter buffers beyond that documented by Atwill et al. (Dayton et al. 2003). Together, the American Water Works Association Research Foundation (AwwaRF) and the Water Environment Research Foundation (WERF) have six projects either completed or in progress to study source, fate, and transport of *Cryptosporidium* and its variability in surface waters.

Studies focusing on wastewater show a 1 to 2-log reduction of *Cryptosporidium* loadings in sewage effluent by conventional wastewater treatment. Wastewater plants with tertiary treatment or polishing filters have observed up to 4.6 log reduction of *Cryptosporidium* oocysts .[26, 27, 28, 29] Additional publications focusing on urban storm water and wastewater also indicate that *Cryptosporidium* oocysts can be significantly reduced through predation by other microbes such as free-living ciliates (i.e. *Paramecium*) in wetland treatment systems.[30] Wetland treatment systems, currently being implemented nationally to address other storm water issues, could prove to be valuable watershed tools for reducing *Cryptosporidium* oocysts in source waters.
In addition to measurable reduction of total *Cryptosporidium* oocyst loadings, the impact of WCPs on loadings of viable and infectious oocysts is important. Reducing these loadings will allow water bodies used for both water supply and recreation to achieve simultaneous benefits and further merge the goals of the CWA and SDWA. Reductions in *Cryptosporidium* viability or infectivity can be obtained through both sophisticated mechanical / structural controls such as

[26] WERF 99-HHE-2– Sources and Variability of Cryptosporidium in The Milwaukee River Watershed.
[27] 1. Suwa, M. and Y. Suzuki, Occurrence of Cryptosporidium in Japan and countermeasures in wastewater treatment plants. Water Sci. Tech. 43(12):183-186, 2001.
[28] 2. Suwa, M. and Y. Suzuki, Control of Cryptosporidium with wastewater treatment to prevent its proliferation in the Water Cycle. Water Sci. Tech. 47(9):45-49, 2003.
[29] Rose, J, L. Dickson, S. Farah, and R. Carnahan. Removal of pathogenic and indicator microorganisms by a full-scale water reclamation facility. Water Research 30(11):2785-2797.
[30] Stott, R., E. May, E. Matsushita, and A. Warren, Protozoan predation as a mechanism for the removal of Cryptosporidium oocysts from wastewaters in constructed wetlands. Water Sci. Tech. 44(11-12):191-198, 2001.

ultraviolet disinfection of wastewater discharges as well as through simpler techniques such as composting manure. Finstein (*in press*) reviews the literature on inactivation of *Cryptosporidium* in animal manure. The data reviewed suggest the feasibility of passive small-scale calf manure composting as a method to effectively inactivate all *Cryptosporidium* oocysts.

Wastewater treatment facilities are currently examining ways to avoid effluent chlorination in order to achieve CWA whole effluent toxicity limits. Integration of ultraviolet disinfection into National Pollutant Discharge Elimination System (NPDES) discharges upstream of drinking water intakes would dramatically reduce infectious oocyst loadings. A study currently in planning by the Philadelphia Water Department aims to measure the effectiveness of ultraviolet disinfection on the viability and infectivity of *Cryptosporidium* oocysts in wastewater discharges upstream of regional drinking water intakes. During studies of wastewater discharges, researchers from Johns Hopkins University and the Maryland DEP observed inactivated or dead *Cryptosporidium* oocysts in wastewater from tertiary or ultraviolet light treated discharges. Results of this work, conducted in conjunction with the Interstate Potomac River Basin Commission, were presented at USEPA headquarters in May 2003 and EPA representatives are receiving project updates.

Though studies demonstrating the impacts of BMPs on *Cryptosporidium* oocysts are limited, data for surrogate indicators are more plentiful. These data provide a basis in the literature for confidence that, when properly implemented, BMPs can lead to meaningful reductions in the amount and infectivity of *Cryptosporidium* oocysts in source water. These surrogate indicators can also be used to select and pilot potentially suitable management practices to evaluate their effectiveness. For example, BMPs effective at removing fine particles or bacteria should also reduce *Cryptosporidium* oocyst concentrations in released water. There are numerous studies and reports sponsored by AwwaRF, WERF, EPA, and the Centers for Watershed Protection demonstrating the effectiveness of numerous BMPs at reducing sediment and bacteria loads to waterways. Inclusion of a compendium of this information in the WCP section of the LT2ESWTR Toolbox Guidance Manual would provide a valuable resource for PWSs developing WCPs.

Request for Comment
Are there confidential business information (CBI) concerns associated with making information on the watershed control program available to the public? If so, what are these concerns and how should they be addressed?

Response
Some of the information referenced in the agency's guidance for WCP would become problematic if made publicly available. Some of the reporting documents for the WCP, as currently described in guidance, may not be suitable for public availability for a variety of reasons. In addition to the concerns outlined below, the effort necessary to generate alternate versions of all WCP technical documents appropriate for sharing with the public would be better put toward developing communication products aligned with the objectives in the WCP Plan.

Some WCP technical documents are working papers that should be shielded as CBI because of the inherent role of partnerships in WCP efforts. Few water utilities hold regulatory control over lands outside their ownership and therefore partnerships are an essential tool in gaining the needed cooperation of neighbors. Utility experience shows that forming partnerships with individuals, groups, businesses, and local governments that are sources of contaminants of concern requires describing how those individuals or entities are impacting the water supply. From that common basis, dialogue and solutions are possible. Developing partnerships is a difficult process and could be easily inhibited or derailed by external entities wishing to employ this information to serve other goals.

Partnerships are the cornerstone of the WCP. They are built on trust and cooperation. Stakeholder trust is earned by providing a safe forum for discussion and negotiation that does not impose otherwise avoidable risk to the parties concerned. Therefore, the AWWA recommends that all WCP documents be considered confidential by default. If a public document is required the utility should have an opportunity to develop a separate, non-sensitive, version free of specific source-related information, focused on program goals, status, and accomplishments.

Request for Comment
How should the "area of influence" be delineated considering the persistence of *Cryptosporidium*?

Response
The area of influence component should be removed from the WCP program document and guidance. Sensitive areas and priority sources will be identified in the vulnerability analysis. Areas for the watershed sanitary surveys should be based upon the utility's proposal and should be flexible enough to accommodate changes on an as-needed basis.

The "area of influence" as defined in the WCP guidance represents all areas except where "*no significant probability of Cryptosporidium or fecal contamination affecting the drinking water intake*" exists. This definition is too broad and subject to interpretation. It assumes an area of vulnerability in which *Cryptosporidium* oocysts quickly reach the intake with little attenuation, dilution, or inactivation (i.e., as one proceeds upstream sources contribute less and less to observed occurrence at the water treatment plant intake). *Cryptosporidium* occurrence is not only a function of the distance between the source of oocysts and the intake but also of the type of source and the amount of oocysts entering the water body. AWWA recommends that the area of influence be described as an area defined by the utility in cooperation with the primacy agency. As a utility's WCP progresses, this area should be re-evaluated based on new information about significant sources of greatest impact, such as source-tracking studies, modeling, or watershed monitoring information.

Detailed Comments on Watershed Control Program Guidance
Appendix 4 contains additional specific comments on the guidance provided regarding watershed control program credit. The comments in the appendix parallel the comments offered above. AWWA recommends the agency revise the draft guidance to reflect the above comments as well as those specifically directed to the guidance manual.

4.2.3 Off-Stream Storage and Alternative Intake

AWWA agrees with the agency proposal that development and implementation of a well-constructed monitoring plan to characterize oocyst occurrence at the alternative intake location and after off-steam storage is the simplest mechanism for identifying the benefit of either of these toolbox components.

4.2.4 Bank Filtration

AWWA is deeply concerned that the proposed rule and guidance being provided to states substantially maligns bank filtration (BF), when in fact, BF is a valuable technology for the U.S. drinking water community. The general tone of the guidance does not encourage utilities to explore or invest in BF when the numerous advantages to bank filtration range from improved water quality to enhanced security.[31]

Available data in the peer-reviewed literature has shown that BF can achieve greater than 1-log removal of multiple surrogates, including algae, diatoms, spores, and the two size ranges (cyst and oocysts) of particle counts. Turbidities resulting from BF are typically lower than the 0.3 NTU required for engineered rapid sand and 1.0 NTU for engineered slow sand filtration.

Current Requirements for Bank Filtration Credit

Automatic 0.5 and 1.0 toolbox credits, including qualification as an upper bin technology (UBT), are available for BF. The peer-reviewed literature including literature cited by the agency in the proposal preamble demonstrate that both the river bed and the aquifer are subject to filtration theory and effectively remove contaminants following processes typical of fate and transport in porous media. Available data from Louisville and Cincinnati on the removal of spores or colloids demonstrate more than 3.0 or 4.0-log removal by bank filtration.[32,33] As proposed, the log credit values are highly conservative, and appropriately designed pilot- or full-scale tests could demonstrate greater log removal credit on a site-specific basis.

Therefore, new BF installations should be allowed to conduct a site-specific study to demonstrate greater log-removal credit. The option to conduct a demonstration should be explicitly stated in the regulatory language, preamble, and associated guidance manual. Such demonstration should not be limited to 0.5 or 1.0 log credit and should not be restricted by the distance measurements identified in §141.726(c). The demonstration study should be based upon sound engineering practice appropriate to the construction of a BF facility (be it vertical, angled, or horizontal well system) with a reliable safe yield, appropriate water quality, and reliably maintained operation.

Bank filtration: A Natural Process

Bank filtration is defined by the guidance manual as a surface water pretreatment process using the bed and bank of a river and the adjacent aquifer as a natural filter and relying solely on the natural properties of the surface water bed and aquifer, unmodified by engineering works or activity, except for the recovery of ground water via a pumping well. This definition of bank filtration characterizes this process by emphasizing natural properties and filtration capacity of the surface water-bed and aquifer. However, throughout the Federal Register and guidance manual, significantly less importance and information is given to the aquifer as far as its

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[31] Weiss et al., Riverbank Filtration – Fate of DBP Precursors and Selected Microorganisms, JAWWA, 95:10, p.68.

[32] Wang, J.Z., S.A. Hubbs, and R. Song. 2002. Evaluation of riverbank filtration as a drinking water treatment process. American Water Works Associations Research Foundation Report 90922, p. 145

[33] Gollnitz, W.D., J.L. Clancy, B. Whitteberry, and J.A. Vogt. Riverbank filtration as a microbial water treatment process. Proceedings of the 2003 AWWA Annual Conference in Anaheim, California.

capability to achieve natural contaminant removal.[34] Bank filtration includes physical, chemical, and biological mechanisms impacting transport and removal of contaminants in porous media. Some specific characteristics of certain zones, such as the riverbed surface or interface, should not overshadow the main characteristics of the aquifer itself. The peer-reviewed literature, including literature cited by the agency in the proposal preamble, demonstrate that both the river bed and the aquifer are subject to filtration theory and effectively remove contaminants following processes typical of fate and transport in porous media.

AWWA recommends that EPA try to better understand BF through a comprehensive review of the primary literature rather than relying on secondary references cited in the proposal. Appendix 5 provides an extended discussion of BF as a filtration process and contains a listing of a number of primary peer reviewed articles that the agency should review and use as it improves its characterization of BF in the finalizing LT2ESWTR.[35]

Scouring

Based on the preamble language, scour is a significant issue for EPA. Scour and fill are two processes that take place when flooding occurs and should not be analyzed separately, but as a combined natural process. Through these scour and fill processes, some sediment is removed and some deposited on the riverbed. In some cases, this process will lead to temporary exposure of the river-bed subsurface, but it will also lead to new sediments being laid over the river-bed subsurface. In fact, scouring and fill should be described as a natural and automatic regeneration of the riverbed interface or riverbed. Scour and fill are a pair of activities that together are beneficial to the BF process when a facility is appropriately sited, allowing BF to achieve good water production both in terms of quality and quantity. Appendix 5 provides an extended discussion of scour and fill phenomena and relate these processes to BF.[36] EPA underestimates the removal provided by the aquifer in the temporary absence of the interface as described in Appendix 5.

LT2ESWTR Compliance Requirements

In the LT2ESWTR compliance requirements, systems that propose to install bank filtration wells to meet any additional treatment requirements imposed by the LT2ESWTR may be eligible for 0.5 or 1.0-log *Cryptosporidium* removal credit (§141.726(c)). In addition to these requirements, the agency should explicitly provide for demonstration of additional credit using a test well. Such a test well should be accompanied by information characterizing the aquifer material. Presentation of a data package summarizing the results from such a study should be adequate to achieve substantial flexibility in the:

1. Design of the collector system employed (i.e., type of collector, well depth, etc.),
2. Siting of the collection facility (i.e., location in the floodplain), as well as
3. Assignment of greater log removal credit.

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[34] LT2ESWTR Toolbox Guidance Manual, Proposal Draft, Section 4., p.. 4-1.

[35] EET, Bank Filtration - LT2ESWTR Toolbox Guidance Manual and Federal Register, Review and Comments, 2003, p 7.

[36] EET, Bank Filtration - LT2ESWTR Toolbox Guidance Manual and Federal Register, Review and Comments, p 1.

AWWA is concerned that the current guidance on BF is incomplete with respect to the above issue of pilot wells. We have several recommendations on BF testing protocols and procedures below, as well as in Appendix 1. EPA should work with AWWA and other stakeholders to improve the guidance for bank filtration and for studies employing test wells as proposed above.

Response to Requests for Comment, 68 FR 47695 §IV(C)(6)(c)

The agency requests comment on the following issues concerning bank filtration on page 47695 of the proposed rule:

Request for Comment

The performance of bank filtration in removing *Cryptosporidium* or surrogates to date at sites currently using this technology (e.g. sites with horizontal wells).

Response

Available data in the peer-reviewed literature has shown that BF can achieve greater than 1-log removal of multiple surrogates, including algae, diatoms, spores, and the two size ranges of particle counts (cyst and oocysts).

Request for Comment

The use of other methods (e.g., geophysical methods such as ground penetrating radar) to complement or supplant core drilling to determine site suitability for bank filtration credit

Response

Development of wells for drinking water supplies is not a new science. Numerous standards apply to development of bank filtration facilities. Bank filtration is a simple technology that the agency should promote, and not hamper by associating it with inordinately difficult to obtain or expensive data acquisition systems or analysis.

Request for Comment

The number of GWUDI systems in each state (i.e., the number of systems having at least one GWUDI source) where bank filtration has been utilized as the primary filtration barrier (e.g., no other physical removal technologies follow); also, the method that was used by the state to determine that each system was achieving 2-log removal of *Cryptosporidium.*

Response

The numerous benefits of bank filtration are recognized throughout Europe and are an important tool to improve water quality from some of the most heavily populated and industrialized waterways in the developed world. Currently, the United States has not adopted bank filtration as widely. The absence of the routine state determinations as described by primacy agencies illustrates why EPA should clearly contemplate BF in the LT2ESWTR. Currently, primacy agency action regarding *Cryptosporidium* is guided by the IESWTR and LT1ESWTR. Neither of these rules specifically addresses bank filtration either in the rule language or in subsequent guidance. Consequently, primacy agencies are unlikely to develop protocols or practices that are not clearly reflected in the federal rule structure.

Request for Comment
For GWUDI systems where natural or alternative filtration (e.g. bank filtration or artificial recharge) is used in combination with a subsequent filtration barrier (e.g., bag or cartridge filters) to meet the 2-log *Cryptosporidium* removal requirement of the IESWTR or LT1ESWTR, how much *Cryptosporidium* removal credit has the state awarded (or is the state willing to grant if the bags/cartridges were found to be achieving < 2.0-logs) for the natural or alternative filtration process and how did the state determine this value?

Response
As was noted in the previous request for comment, currently primacy agency action regarding *Cryptosporidium* is guided by the IESWTR and LT1ESWTR. Neither of these rules specifically addresses bank filtration either in the rule language or in subsequent guidance. Consequently, primacy agencies are unlikely to develop protocols or practices that are not clearly reflected in the federal rule structure. This dampening of individual state initiative results from federal regulation and is delaying development of bank filtration in the United States.

Request for Comment
Any additional information related suitable separation distance(s) to be required between vertical or horizontal wells and adjacent surface water.

Response
The proposed criteria require new BF wells seeking credit under LT2ESWTR to be located outside the 100-year flood plain. The agency should recognize that currently wellheads can be located within the 100-year floodplain and are readily designed and permitted. At many potential sites, the proposed separation will preclude construction of wells with adequate safe yields needed to justify investment in BF systems. Consequently, the proposed criteria are not engineering safeguards but rather provisions designed to limit the applicability of BF. Given the conservative approach employed in the BF default credit criteria, the rule and guidance should clearly provide for the conduct of appropriate studies to demonstrate as much as 5.5-log removal. Such demonstrations should be allowed using pilot well or full-scale facilities. The opportunity to demonstrate performance at sites with less separation from the water body than reflected in the default credits is essential.

Request for Comment
Any additional information related to testing protocols and procedures for making site-specific determinations of the appropriate level of *Cryptosporidium* removal credit to award to bank filtration processes.

Response
The objective of pilot testing where a permanent production well is not yet installed is to demonstrate that a site will result in more than the given 0.5 to 1.0-log removal given by nature of the default credit.

Most utilities complete pumping tests prior to final wellfield design to develop aquifer characteristics of conductivity and specific storage. These values, along with particle size distributions of the aquifer at various depths, will provide a great deal of insight into the capability of the aquifer to filter particles. Riverbed particle size distributions are also helpful in characterizing the BF system.

If additional demonstration of *Cryptosporidium* removal is desired, it may be feasible to extend the pumping test with additional observation wells located along the shortest flowpath to the stream. Given the aquifer characteristics, estimating the time of travel along this flowpath to the observation wells and production well is possible. At the point in time where this flowpath is indicating the influence of river water, water quality characteristics can be monitored to gain an indication of the aquifer's ability to remove particles.

Temperature can be an effective parameter to estimate the time of travel between the stream and the observation wells. Turbidity and spore data can be effective measures of particle removal for estimating *Cryptosporidium* removal. Appendix 1 includes an example demonstration of BF removal using spore data.[37] Usually the impact of groundwater dilution of the stream infiltrate at the production well limits the use of this well for estimating long-term particle removal, as transient conditions may persist for months. Thus, the monitoring well closest to the stream source must be large enough to produce a sample volume adequate for the desired analysis.

Request for Comment
Information on the data and methods suitable for predicting *Cryptosporidium* removal based on the available data from surrogate and indicator measurements in water collection devices.

Response
Data reported in the literature for pilot-scale microbial spiking studies indicate that *Cryptosporidium* is typically removed more readily than aerobic spores during physical treatment process such as clarification and filtration. Appendix 2 is a report prepared by EET for AWWA that summarizes the relevant literature demonstrating this point.[38] Work by Neiminski and Bellamy (2000) [previously referenced], as well as other literature summarized in Appendix 2, demonstrates that aerobic spores are naturally occurring in surface waters and are readily monitored using available analytical methods.[39] Other characteristics of aerobic spores include:

1. Can be detected at very low concentrations (<1cfu/100mL),
2. Are about the same size as *Cryptosporidium*,
3. Do not undergo regrowth, and
4. Are frequently found at levels high enough to demonstrate removal.[40]

Given these attributes, which are appropriate for evaluating removal processes, and that aerobic spores are a conservative measure of removal, AWWA recommends that the agency explicitly

[37] EET, LT2ESWTR Treatment Requirements, Cryptosporidium Monitoring, Bin Assignment, Core Treatment, And Microbial Toolbox, p. 64.
[38] EET, LT2ESWTR Treatment Requirements *Cryptosporidium* Monitoring, Bin Assignment, Core Treatment, And Microbial Toolbox, 2003
[39] EET, *Cryptosporidium* Removal Credit Assignable In The LT2ESWTR Toolbox, 2001
[40] EET, *Cryptosporidium* Removal Credit Assignable In The LT2ESWTR Toolbox, 2001. [Note that this report includes references to primary literature as well as summary graphics.]

recognize aerobic spores as a surrogate measure in removal studies under the LT2ESWTR including processes like BF.

In finalizing the LT2ESWTR, EPA should not, however, foreclose the use of other analytical methods to demonstrate removal. Some source waters do not contain enough naturally occurring aerobic spores to demonstrate the levels of removal required by the LT2ESWTR. Consequently, the agency should be open to considering demonstrations based on other types of surrogates such as turbidity, particle counts, or another microbial indicator.

Request for Comment
The applicability of turbidity monitoring or other process monitoring procedures to indicate the ongoing performance of bank filtration processes.

Response
Turbidity monitoring at bank filtration system wellheads or at the combined effluent from a group of bank filtration system wells is an appropriate monitoring procedure to monitor the ongoing performance of bank filtration processes. Turbidities from BF systems are typically lower than the 0.3 NTU required for engineered rapid sand and 1.0 NTU for engineered slow sand filtration.

Detailed Comments on Bank Filtration Guidance
Appendix 6 contains additional specific comments on the guidance provided regarding BF. The comments in the appendix parallel the comments offered above and address additional detailed issues. AWWA recommends the agency revise the draft guidance to reflect the above comments as well as those specifically directed to the guidance manual.

4.2.5 Enhanced Filtration (CFE Credit)

Value of Conventional Treatment Compliant with IESWTR
The Stage 2 M/DBP FACA recommendations and the agency's LT2ESWTR proposal credits for additional *Cryptosporidium* reduction are premised on the assumption that existing direct filtration and combined clarification-plus- filtration facilities complying with the IESWTR (or LT1ESWTR) achieve at least 2.5- and 3.0-log removal, respectively. In setting this baseline, the FACA members recognized that many of these facilities achieve higher levels of *Cryptosporidium* removal.

The microbial toolbox was intended to provide a wide selection of alternatives for plants to use to demonstrate or establish *Cryptosporidium* protection capabilities. The proposed alternatives included existing treatment technologies as well as some new technologies that might be added to plants to obtain *Cryptosporidium* removal credit. The peer-reviewed literature includes data indicating that for some treatment systems, compliance with the IESWTR may translate into 4.0-log, 5.0-log, or higher *Cryptosporidium* protection potential, not just the 2.5- or 3.0-log default credit allowed for a conventional filtration plant. One objective of the microbial toolbox is to provide realistically defined *Cryptosporidium* protection credits so that a facility in compliance with the IESWTR that achieves more than 2.5- or 3.0-log of protection can demonstrate or establish the higher treatment capability of the treatment plant.

Data available during development of the IESWTR and LT1ESWTR indicated that combined clarification-plus-filtration treatment, or filtration alone (i.e., direct filtration), achieved at least 2-log *Cryptosporidium* removal. Studies published in the literature since then, coupled with a re-evaluation of earlier data, indicate that conventional clarification-plus-filtration systems operating to meet IESWTR or LT1ESWTR requirements (turbidity ≤0.3 NTU) achieve mean and median *Cryptosporidium* removals of 4 to 6 logs. These data are summarized in Table 2. True removal capabilities for these tests are likely to be greater than indicated in Table 2 because filtered water *Cryptosporidium* concentrations were usually below detection limits in these studies (see last column of table). Below-detection values limit the demonstrated removal levels. Similarly, direct filtration studies typically demonstrated mean and median *Cryptosporidium* removals exceeding 2.5-log.

Table 2. Impact of Achieving IESWTR Required Effluent turbidity (<0.3 NTU) on Log Removal of *Cryptosporidium* During Treatment with Clarification Plus Filtration or Direct Filtration Alone

Literature Source	*Cryptosporidium* Log Removal Data				Percent of Filtered Data <DL
	N	Mean	Median	Range	Percent
Clarification + filtration					
States et al. 2002	15	5.8	6.0	6.6-2.3	26.7
Cornwell et al. 2000	44	5.2	5.3	6.0-3.1	55.6
Hall et al. 1994	33	4.8	5.1	6.5-2.9	63.6
Dugan et al. 2001	6	4.9	5.0	5.2-4.5	17.1
Patania et al. 1995	63	4.3	4.3	6.0-2.6	17.5
McTigue et al. 1998	115	4.0	4.0	5.6-1.5	7.8
Nieminski and Bellamy 2000	138	*			
Direct filtration					
Swaim et al. 1996	12	3.8	3.6	4.4-3.3	25.0
Patania et al. 1995	24	2.9	2.9	4.0-1.5	29.2
Ongerth and Pecoraro 1995	3	3.0	2.8	3.4-2.7	0.0
West et al. 1994	4	3.1	3.3	3.4-2.6	

Notes: * Only eight events employed filtered water detection limits low enough to mathematically demonstrate ≥3-log removal associated with the raw water concentration present.
N= number of observations

The agency's summary of the available literature does not adequately reflect the conservatism underlying the default log removal credits recommended by the negotiating committee. Toolbox credits for enhanced filtration and demonstration of performance under the LT2ESWTR framework should provide credible and feasible means for treatment plants to obtain the level of credit appropriate for their operational performance when that performance exceeds the minimum baseline assumptions.

Improved *Cryptosporidium* Removal at Turbidity Below 0.15 NTU

EPA asks if available studies cited here support awarding 0.5-log credit for CFE < 0.15 NTU 95% of the time.[41] Data reported by Huck et al. (2002) (referenced in LT2ESWTR preamble) from separate pilot-scale studies conducted in Ottawa and Southern California provide the most unambiguous demonstration of the improvement in *Cryptosporidium* removal associated with reduction of filter effluent turbidity form 0.3 to 0.15 NTU. The information from the Ottawa and California studies reported by Huck et al. (2002) are listed in Appendix 1. These data reflect log removal calculated for each pair of filter influent and effluent samples reported from these studies. The Ottawa data demonstrated a >3 log improvement in the median calculated log removal when filter effluent turbidity was <0.15 NTU versus when turbidity was between 0.15 and 0.3 NTU. Similar reduction in turbidity resulted in an improvement of 1.8 log for median removal in the California studies.

Appendix 1 summarizes data for other full- and pilot-scale studies published in the literature. Most of the other data cited in this table either has a limited number of results in one or both groups, or includes data where the true difference in removal between the two groups can not be numerically established with the filtered water detection limits used, given the low raw water occurrence. The few situations where a comparison between <0.15 NTU versus between 0.15 and 0.3 NTU can be made indicate a difference in log *Cryptosporidium* removal of >0.7-log to >3-log.

As previously described, available experimental data in the peer review literature indicate that existing facilities with clarification and filtration in compliance with the IESWTR can achieve 4.0, 4.5, or higher log removal of *Cryptosporidium*. The 1.0, 1.5, or greater correction of the minimum 3.0 baseline credit can be partially provided by the CFE and IFE credits. These credits both involve providing additional *Cryptosporidium* protection credits when the filter effluent turbidity improves from 0.3 to 0.15 NTU. Existing literature contains evidence demonstrating that improvements in effluent turbidity from 0.3 to 0.15 NTU translates to an improvement in *Cryptosporidium* removal of more than 1.5 log.

Response to Requests for Comment, 68 FR 47700 §IV(C)(8)(c)

The above discussion addresses all but one of the specific requests for EPA raises in the preamble. The following request for comment is directed to practicality of using available methods and instruments to reliably measure turbidity at or below 0.15 NTU.

Request for Comment

Does currently available turbidity monitoring technology accurately distinguish differences between values measured near 0.15 NTU?[42]

Response

As noted in the LT2ESWTR preamble, the method development process undertaken by the American Society for Testing and Materials (ASTM) has produced a practice for on-line instruments and a standard for static instruments measuring turbidity in the region of interest for both the proposed CFE and IFE credits. The ASTM method development process was robust

[41] 68 FR 47700
[42] 68 FR 47700

and data generated through the practice and method development effort demonstrated that appropriate levels of accuracy and precision can be maintained to support implementing regulatory requirements at 0.15 NTU. While on-line turbidimeters are robust instruments, when in use continuously for years, bubbles, noise in SCADA electronics, and other factors will inevitably result in erroneous reported values. Compliance algorithms should not be so stringent as to identify transient lapses in the measurement and recording electronics to result in compliance violations.

4.2.6 Peer Review (IFE) Credit

EPA requests comment in the Federal Register preamble on whether peer-review programs exist and if different or additional performance measures should be required to meet the 1.0-log additional credit.[43] As described below, the microbial toolbox in the Stage 2 M/DBP Agreement in Principle includes a 1.0-log credit for peer review programs. The Agreement in Principle specifically cites the Partnership for Safe Water (PSW) Phase IV as an example. At the time of the Agreement in Principle, PSW Phase IV program could be described as:

1. Having aggressive numeric goals that serve as objectives for water treatment plants to seek to achieve,
2. Engaging peers or technical consultants to review data, reports, and inspect applicant facilities,
3. Committing to continuous improvement management strategy, and
4. Employing the Composite Correction Program (CCP) process.

The PSW Phase IV program did (and does) not rigidly require participants to achieve fixed numeric criteria. This distinction is critical when compared to traditional regulatory frameworks. PWS's numeric criteria are goals against which compliance is measured given local water quality and operational constraints. The goal of PSW participation is not to meet numeric targets but to undertake the management and operational changes that will enhance performance of the drinking water facility. Gross departures from the numeric goals or repeated failure to achieve the goals cause a utility to be denied approval for Phase IV of the PSW but the primary purpose of the numeric criteria are as goals. The PSW and similar programs aim to raise the overall performance of their participants. These programs are not geared toward identifying violations or requiring strict adherence to numeric criteria. This wholly different outlook on reporting and recordkeeping is a factor that must be reconciled with traditional regulatory approaches if the enhanced filtration element of the microbial toolbox is to be appropriately developed in the final LT2ESWTR.

The FACA Agreement in Principle included a 1.0-log credit for peer-review programs, such as Phase IV review under the PSW. The original intention of the peer-review credit was to reward utilities that have already undergone such peer-review processes as Phase IV of the PSW, and to also encourage other utilities to undergo these same activities in the future. The recognized benefits of the peer-review process include independent review and feedback from outside parties involved in the process. Perhaps a more important benefit is the activities and

[43] 68 FR 47714

improvements to infrastructure and operational practices initiated internally by the utilities themselves to reach their goals. The benefits of a peer-review process such as Phase IV of the PSW, and one of the main justifications for the associated 1.0-log credit, was the depth and breadth of consequences from activities associated with meeting the Phase IV goals. These improvements would directly increase microbial protection and improve filtered water quality, but would also involve comprehensive improvements throughout the entire process (watershed through filtration). Therefore, the 1.0-log credit was partially for comprehensive improvements in treatment performance, not just for an increase in microbial protection. Information provided by the PSW indicates that utilities that are involved with this process do improve treatment operations, including filter performance. For example, all plants that have achieved PSW Phase III status have improved 95th percentile CFE values, and most have reduced the frequency, duration, and magnitude of turbidity spikes.

However, since the PSW has dropped on-site, third-party peer review from the Phase IV requirements, EPA believed, perhaps rightly, that PSW Phase IV should not be directly reflected in the proposed LT2ESWTR, and did not include the peer-review credit as an option. EPA replaced it with an IFE credit based on a one of the numeric goals of Phase IV of the PSW (a criteria that PSW has since abandoned).

The IFE credit proposed by EPA, though numerically similar to the criteria formerly used by the PSW, does not included an essential ingredient in the Phase IV PSW process, the third party peer review. In the PSW process, expert review allows award of Phase IV status to water treatment plants that do not necessarily achieve the numeric IFE goal. Conversely, meeting the numeric IFE goal does not guarantee award of Phase IV status.

Analysis conducted for AWWA indicated that the IFE credit proposed in the LT2ESWTR is not achievable at U.S. utilities, even at well-operated facilities such as those in PSW. This assessment is described in some detail in Appendix 1. This analysis has led AWWA to return to the Stage 2 M/DBP FACA's intent when it endorsed establishing a credit for peer-review programs. While most agree that PSW should not become a regulatory program, participation in PSW and other similar peer-review programs offer an important mechanism to enhance treatment performance beyond levels typical of the average IESWTR compliant facility. EPA's Composite Correction Program (CCP) is the underlying methodology for PSW and the principle source of the PSW's original numeric targets. The CCP program is at the heart of the PSW program, but PSW is not the only program to employ the CCP program. Individual state programs and EPA's own Area-Wide Optimization Program (AWOP) are based on the CCP process.

AWWA endorses the microbial toolbox credit for successful participation in peer review programs. The proposed peer-review credit would provide 0.5-log credits for state approved peer-review programs. AWWA proposes that an alternative 0.5-log credit be available for utilities where recognized programs are not available, and for utilities that do not choose to participate in such voluntary peer review programs. The proposed numeric criterion is achieving 0.15 NTU or less in 97 percent or more of observations taken at the CFE based on 15-minute observations and computed on a monthly basis.

Peer Review Programs Do Exist

In the fall of 2000, the PSW modified the peer-review component from its Phase IV program. Therefore this program is substantially different from the peer-review component of the toolbox as outlined in the Agreement in Principle. In 2003, the PSW modified the Phase IV individual filter turbidity goal to 0.10 NTU 95 % of the time for each operating filter, calculated monthly and based on all 15-minute readings during filter runs. Standard arithmetic rounding rules apply. Currently, two facilities in the United States meet Phase IV PSW goals and have been recognized as complying with this and other applicable criteria. AWWA is not aware of a similar independent national model having the same characteristics as the PSW Phase IV program.

A number of more localized programs are similar to the PSW Phase IV (circa. 2000). These programs entail each of the program characteristics described above though specific numeric goals are more apt to parallel the CCP program than the PSW. Two programs that have been frequently cited as models are the Texas Optimization Program and the Area Wide Optimization Program (AWOP) that has been used extensively in Kentucky. The Texas Optimization Program is based on individual filter turbidity limits. The AWOP program is substantially based on the CCP program drafted by the EPA drinking water program. The SDWA primacy agency operates both programs. Both are voluntary and rely primarily on peer-to-peer communication to assist participants in achieving improved operations. Based on Kentucky's success in improving operations at drinking water utilities that were encountering operational or management challenges, EPA is encouraging EPA Regions to promote the AWOP concept nationwide.

A Suitable Numeric Standard is Needed

The PSW eliminated the peer-review component from Phase IV, the program under the EPA AWOP initiative is not nationally applied, and only a few states sponsor peer-review programs. Consequently, a microbial toolbox component based solely on approval through an appropriate peer-review program is not equally available to all utilities. Therefore, EPA should supplement the peer-review log-credit with a separate but equal numeric criteria reflected explicitly in the LT2ESWTR and associated LT2ESWTR guidance.

The IFE credit as currently defined in the proposal is too restrictive and inappropriate for facilities attempting to achieve this credit and that are well operated facilities deserving of the defined credit. The current IFE credit includes two provisions. One provision requires 95 percent of the daily maximum observations to be <0.15 NTU each month. The daily maximum is the largest of the 96 turbidity readings collected at 15-minute intervals from midnight to midnight at a single filter. The second provision disallows the credit if any filter during a month has two consecutive 15-minute readings >0.349 NTU. Even considered separately, these provisions are unrealistically restrictive and cannot be achieved consistently by facilities where the 1.0-log credit is appropriate.

Several alternatives to the current IFE credit are evaluated in Appendix 1. Several alternatives considered provide improvement but remain too restrictive. For example, replacing the daily maximum (i.e., maximum of 96 daily 15-minute readings) with all 15-minute data (i.e., all 96 daily data points) as the basis for the 95th percentile limit still renders the credit achievable for water treatment plants where the performance credit correction is appropriate.

Alternatives for enhanced filtration credits, which seemed most appropriate, based upon AWWA's review of the available data, include the following:

1. Keep current CFE credit as currently defined (0.5 credit).
2. Keep current definition of CFE credit, but increase the credit from 0.5 to 1.0 credit.
3. Convert current CFE credit into a two-tiered credit. The current definition of the CFE credit will be used as the first tier, and will continue to be allowed a 0.5 credit. The second tier would be an additional 0.5 credit, or a total of 1.0 credits, for facilities meeting CFE 97 percent <0.15 NTU. The IFE credit would be eliminated.

Increasing the CFE to a 97-percent compliance level is a strict requirement, supportable by the literature described earlier that indicates a <0.15 NTU filtered turbidity shows >1.0 long improvement in *Cryptosporidium* removal. At a 95-percent compliance level, a plant can operate between 0.15 NTU and 1.0 NTU for 36 hours during a month. That time is reduced to 20 hours, or almost in half, by increasing the compliance level to 97 percent. This additional credit is consistent with the literature and with EPA's goal of having systems produce more consistent water at a lower turbidity. This CFE regulatory provision is consistent with current regulations that utilities and states are familiar with implementing. In addition, AWWA believes that the IESWTR reporting provisions for IFE are suitable to address any potential problems with individual filters.

Alternative 3, which is based on CFE rather than IFE criteria, offers the added benefit of greater equity when applied across the breadth of plant sizes and designs. IFE criteria by definition place a greater burden on plants that have more filters because of their design or because of their size. This differential can be substantial. As a consequence, the likelihood of failing to comply with the criteria rises with the number of filters in operation. The CFE based alternative does offer significant advantage in minimizing reporting and data management burdens for states.

Additive Credit is Easier to Implement

The current rule defines the CFE credit as a 0.5-log credit and the IFE credit as a 1.0-log credit that cannot be used in combination with the CFE credit. The net maximum credit is 1.0-log credit. The same net effect can be achieved more simply by defining the two credits as separate 0.5-log credits that can be combined, thereby still resulting in a maximum 1.0-log credit. This revision would substantially improve the current definition, which is confusing.

Section 141.727 indicates "Systems may not claim credit under this paragraph [combined filter performance] and paragraph (b) [Individual filter performance] in the same month." With this construct, EPA is implicitly recognizing that a water treatment plant may meet its LT2ESWTR log-credit requirements one month by complying with IFE criteria and then, when failing to make IFE, by complying with CFE. A more transparent approach to these two criteria would be assignment of independent 0.5-log credits to each performance target. This approach would be more straightforward both in terms of implementation and interpretation.

Response to Requests for Comment, 68 FR 47695 §IV(C)(16)(c)

The following are several requests for comments that bear on IFE credit, which the above comments do not directly address. Responses are provided for each.

Request for Comment
Are there existing peer review programs for which treatment credit should be awarded under the LT2ESWTR? If so, what role should primacy agencies play in establishing and managing any such peer review program?[44]

Response
AWWA directly addressed the first half of this request for comment earlier in this section. The latter question is clearly a question that will need to be answered on a program-specific basis. The state primacy agency must not necessarily be directly involved in a peer-review program or for primacy agency to "manage" such a program. Primacy agencies do operate such programs, such as Texas' program that is modeled after the PSW and the Composite Correction Program (CCP). A peer-review program can function just like any other independent standards group (i.e., ISO, Standard Methods, ASTM, ASCE, ASM, etc.) outside the umbrella of regulatory supervision. Congress encouraged integration of non-governmental standard bodies through such statutes as the National Technology Transfer and Advancement Act.

The relevant primacy agencies must recognize that participation in the program meets the agency's expectations regarding obtaining credit under LT2ESWTR. Consequently, a primacy agency should clearly state the metrics by which it judges such peer-review programs in the context of LT2ESWTR. Such metrics might include:

1. A written set of performance standards or goals,
2. Integration of the goals and objectives and similar processes to the CCP,
3. An independent or multi-stakeholder managing board,
4. Preparation of an annual report containing metrics of performance for participating utilities,
5. Preparation of a quarterly or annual report of participating utilities,
6. The preparation of a formal written report summarizing peer review findings on applicant's acceptance into program,
7. Written reports that document any approved deviation from the program's performance standards or goals,
8. Minimum expectations for data management, and
9. An internal or third party audit of both the peer-review organization's finances and review process.

Primacy agencies electing to develop an internal "peer-review" program should seriously consider applying the metrics above to their own programs. With or without such performance metrics, operating or managing a peer-review program will be taxing on primacy organizations. Recognizing third-party organizations to provide this service is a good example of how agencies can outsource well-defined, special-purpose programs.

[44] 68 FR 47714

Request for Comment
Whether 0.15 NTU should be the standard for individual filter performance credit, as this would be consistent with the standard of 0.15 NTU that is proposed for combined filter performance credit in section IV.C.8.[45]

Response
If the agency were to pursue an individual filter performance criterion in the absence of a peer-review program, an approach for which AWWA has proposed a credible and fairer alternative, then 0.15 NTU is more appropriate than 0.10 NTU (see above discussion and Appendix 1) regarding demonstrated removals achieve when filtration achieves 0.15 NTU.

Comments on Guidance Manual

EPA provided a Draft LT2ESWTR Toolbox Guidance Manual for review with the LT2ESWTR. AWWA considered both the regulatory language and associated guidance in drafting its comments. AWWA recommends that EPA respond to the comments in this section by modifying Chapter 7 of that Guidance manual.

4.2.7 Pre-sedimentation

As defined in §141.730 of the proposed LT2ESWTR, the pre-sedimentation default 0.5-log credit is achieved through a clarifier or retention basin which is (1) continuously operated, (2) located prior to point at which the entire water treatment plant flow reaches the “treatment plant”, (3) coagulant is added when unit is operating, and (4) demonstration of 0.5-log turbidity reduction. While AWWA agrees with the first three components of these criteria, the fourth is not routinely demonstrable and does not reflect the overall benefits obtained through pre-sedimentation.

Conventional drinking water treatment processes are operated in such a way as to match treatment to influent water challenge, in this instance, particle removal. While the coagulation-flocculation-clarification-filtration process is robust, an important operational goal is process stability. Pre-sedimentation is a useful tool in managing the initial particulate load reaching the primary treatment process. Pre-sedimentation not only begins the solids removal process, it also helps to equalize water quality reaching the primary treatment process. Moreover, when coagulant addition is occurring and the treatment process is being actively managed to achieve clarification, solids removal achieved in pre-sedimentation reduces the solids load on the primary clarification process in the water treatment plant. The water treatment plant can operate the two processes in a complementary fashion so that the overall treatment process is less dependent on the removal of the solids overflow during filtration.

Available data suggest that pre-sedimentation basins located prior to a point at which raw water flow reaches the principal treatment train, and that are continuously operated using a coagulant (polymer, metal salts, or recycled sludge), should receive a 0.5 credit at overflow rates up to 1.6 gpm/ft^2.

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[45] 68 FR 47714

The exact data that was used by the Science Advisory Board Drinking Water Committee when it drafted its recommendations on pre-sedimentation credit is not completely clear. As defined in §141.730, pre-sedimentation is functioning much like conventional clarification, except that pre-sedimentation is only intended to meet pretreatment objectives, and consequently will often operate at higher overflow rates than conventional clarification. Data are available in the peer-reviewed literature demonstrating 1-log and greater *Cryptosporidium* removal with conventional clarification (Edzwald et al., 2000; Cornwell and MacPhee, 2001; Cornwell, et al., 2001; Edzwald and Kelley, 1988; Plummer et al., 1995; Dugan et al., 1999; Hall et al., 1994; Patania et al., 1995; and others).[46, 47, 48, 49, 50, 51, 52, 53] While the peer-reviewed literature (Appendix 7) provides a sound foundation for this log credit, data collected and supplied with these comments from four drinking water treatment plants operating pre-sedimentation processes likewise demonstrate substantial removal of a surrogate organism, aerobic spores.

EPA solicits additional data supporting the pre-sedimentation credit.[54] Personnel at four drinking water plants operated by three U.S. utilities (in St. Louis, Mo.; Kansas City, Mo.; and Cincinnati, Ohio) have independently collected data regarding the removal of *Cryptosporidium* and spores (*Bacillus subtilis* and total aerobic spores) during operation of full-scale pre-sedimentation basins. This data collection effort is an extension of the data collection effort cited in the LT2ESWTR preamble.[55] *Cryptosporidium* oocysts were rarely detected in raw water at these locations and, consequently, calculating oocyst removal through these processes was not possible. Aerobic spores were detected more readily in raw water than were *Cryptosporidium*, making it possible to calculate log removal of spores at these three utilities.[56] The observed spore removal rates clearly demonstrate that, with coagulant addition, greater than the 0.5 log of removal can be routinely expected from such facilities.

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[46] Edzwald, J., J. Tobiason, L. Parento, M. Kelley, G. Kaminski, H. Dunn, and P. Galant. 2000. Giardia and *Cryptosporidium* Removals by Clarification and Filtration Under Challenge Conditions. JAWWA. 92(12):70-84.
[47] Cornwell, D. and M. MacPhee. 2001. Effects of Spent Filter Backwash Recycle on *Cryptosporidium* Removal. JAWWA. 93(4):153-162.
[48] Cornwell, D., M. MacPhee, N. McTigue, H. Arora, G. DiGiovanni, and J. Taylor. 2000. Treatment Options for *Giardia, Cryptosporidium*, and Other Contaminants in Recycled Backwash Water. Denver, CO: AWWARF and AWWA.
[49] Edzwald, J., and Kelley, M., 1998. Control Of *Cryptosporidium*: From Reservoirs To Clarifiers to Filters. Water Science and Technology. 37(2):1-8.
[50] Plummer, J., J. Edzwald, and M. Kelley. 1995. Removing *Cryptosporidium* by Dissolved-Air Flotation. JAWWA. 87(9):85-95.
[51] Dugan, N., K. Fox, R. Miltner, D. Lytle, D. Williams, C. Parrett, C. Feld, and J. Owens. 1999. Control of *Cryptosporidium* Oocysts by Steady-State Conventional Treatment. Proc. Of 1999 Annual Conference. Denver, CO: AWWA.
[52] Hall, T., Pressdee, J., and Carrington, N. 1994. Removal of *Cryptosporidium* Oocysts by Water Treatment Process. London, England: Foundation for Water Research Limited.
[53] Patania, N., J. Jacangelo, L. Cummings, A. Wilczak, K. Riley, and J. Oppenheimer. 1995. Optimization of Filtration for Cyst Removal. Denver, CO: AWWARF and AWWA.
[54] 68 FR 47691
[55] 69 FR 47689
[56] All three utilities use analytical procedures similar to those described in Rice et al. 1996 to quantify *Bacillus subtilis* and other aerobic spores. *Cryptosporidium* and *Giardia* samples were analyzed using the ICR Method (USEPA 1996) prior to Summer-Fall 2000, and Method 1623 (USEPA 1999) thereafter.

Table 3. Summary of Spore Removal Data at Four Pre-Sedimentation Facilities

Observations		Facility A 2002	Facility A 2003	Facility B 1998-2000	Facility B 2003	Facility C[3] 2001-2002	Facility C[3] 2003	Facility D 1996-2003
Number of Observations		1,112	225	273	68	268	63	325
Median Log Removal of Paired Data[1]		0.59	0.69	0.79	0.73	0.45	1.68	0.60
Median Concentration (Spores /L)[2]	Raw	165,000	255,000	290,000	435,000	300,000	377,778	90,000
	Pre-sedimentation	48,000	64,000	61,750	101,000	138,333	9,067	19,000
	Median Log Removal	0.54	0.60	0.67	0.63	0.34	1.62	0.68

Notes: [1] "Median log removal of paired data" is the median of log(in/out)
[2] "Median log removal" is calculated as log (median in/median out).
[3] Improved removal over time at facility C reflects changes in operational practice.
For multiple columns of data for a given facility, the first column reflects a period of record previously reported to EPA and the second reflects additional data.

This same data collection effort also included turbidity data from Facilities B and C. Despite providing or exceeding desired levels of spore removal, these facilities were not able to reliably demonstrate 0.5-log turbidity removal on a monthly basis. In part, the level of influent turbidity limits demonstrating 0.5-log turbidity removal. If influent turbidity levels are low, then the solids load is not sufficient to support the required demonstration. AWWA believes this practical limitation on the 0.5-log turbidity removal renders this rule provision unsound. Rather, the agency should proceed with a default 0.5-log credit for pre-sedimentation that is (1) continuously operated, (2) located prior to point at which the entire water treatment plant flow reaches the "treatment plant", (3) coagulant is added when unit is operating, and (4) maintain overflow rates less than or equal to 1.6 gpm/ft^2.

Response to Requests for Comment, 68 FR 47691 §IV(C)(5)(c)

The agency requests comment on the following issues concerning pre-sedimentation on Page 47691 of the proposed rule:

Request for Comment

Whether the information cited in this proposal supports the proposed credit for pre-sedimentation and the operating conditions under which the credit will be awarded.

Response

AWWA believes that the data included in the preamble, in combination with the information provided in these comments, is adequate to support a 0.5 credit when pre-sedimentation is (1) continuously operated, (2) located prior to point at which the entire water treatment plant flow reaches the "treatment plant", (3) coagulant is added when unit is operating, and (4) maintain overflow rates less than or equal to 1.6 gpm/ft^2.

Request for Comment

Today's proposal requires systems using pre-sedimentation to sample after the pre-sedimentation basin, and these systems are not eligible to receive additional presumptive *Cryptosporidium* removal credit for pre-sedimentation. However, systems are also required to collect samples prior to chemical treatment, and EPA recognizes that some plants provide chemical treatment to water prior to, or during, pre-sedimentation. EPA requests comment on how this situation should be handled under the LT2ESWTR.

Response
Detailed comments on LT2ESWTR monitoring for source water bin determination are provided in Section 4.1. In response to this specific request for comment, EPA should make the revisions to the monitoring location requirements described in Section 4.1. In making these corrections, EPA should continue to encourage monitoring under §141.702(e) to take place after existing pre-sedimentation basins (as well as BF and off-stream storage) when such facilities are in place. EPA should also provide a mechanism for monitoring prior to these technologies when appropriate and especially with respect to pre-existing data submitted under §141.708.

With respect to chemical treatment during pre-sedimentation interfering with monitoring observations, EPA Method 1623 is a performance-based method which includes a number of components geared toward ensuring that the laboratory can provide enumeration across a range of matrices, including pre-sedimentation clarifier effluent. Some of these components include:

1. Matrix spikes to assist the laboratory to make changes to accommodate the characteristics of particular samples,
2. Ability to use a range of sampling procedures including use of a range of filters, and
3. Latitude to modify the method within the bounds of demonstrated performance via Tier I or II studies as outlined by Office of Science and Technology for verification of method modification.

Method requirements are imposed by the LT2ESWTR §141.705(a)(1), which include obtaining a minimum sample volume. This sample volume is ensured through requirement to take a 10-liter sample or processing a minimum of 2 ml of packet pellet. Section 141.705 also includes provision that utilities must process a minimum number of two filters.

Request for Comment
Whether and under what conditions factors such as low-turbidity raw water, infrequent sludge removal, and wind would make compliance with the 0.5-log turbidity removal requirement infeasible.

Response
If influent turbidity levels are low, then the solids load is not sufficient to support the required demonstration. AWWA believes this practical limitation on the 0.5-log turbidity removal renders this rule provision unsound. The agency should proceed with a default 0.5-log credit for pre-sedimentation that does not include a turbidity removal criterion. Appropriate criteria are (1) continuously operated, (2) located prior to point at which the entire water treatment plant flow reaches the "treatment plant", (3) coagulant is added when unit is operating, and (4) maintain overflow rates less than or equal to 1.6 gpm/ft^2.

Comments on Guidance Manual

EPA provided a Draft LT2ESWTR Toolbox Guidance Manual for review with the LT2ESWTR. AWWA considered both the regulatory language and associated guidance in drafting its comments. AWWA recommends that EPA respond to the comments in this section, as well as Section 4.1.1, by revising Chapter 5 of that Guidance manual.

4.2.8 Softening

EPA has appropriately and accurately summarized the available literature. Available data indicate that a typical single-stage softening process routinely provides as much, or more, *Cryptosporidium* removal as traditional coagulation-clarification-filtration treatment processes. Consequently, drinking water treatment plants that practice lime softening should achieve an average 3-log removal of *Cryptosporidium*, as was assumed for other clarification and filtration treatment ("conventional") plants in the Bin Requirements Table of the Stage 2 M/DBP Agreement in Principle. When a secondary clarification step is included in a treatment process, such as with two-stage softening, available data suggest that the second clarification step provides increased redundancy and stability to the treatment train, plus an additional treatment barrier to the passage of protozoa into the potable water supply. Consequently, an additional 0.5-log credit is appropriate for two-stage softening and other plant designs that employ multiple, continuously operated, clarification processes in series.

EPA specifically asks for any new or additional information that would contribute to the softening log removal credit. Several full-scale softening facilities have ongoing monitoring programs whose data has been collected over the last year. Appendix 1 contains a summary of these data. Initial findings from this data collection effort are reflected in a recently published article.[57]

Addition of a Coagulant

Section 141.726(b) provides for a 0.5-log credit for two-stage lime softening if:

1. A second clarification step is located between the primary clarifier and filter(s), and
2. This second clarification step is operated continuously, and
3. Both clarifiers treat all of the plant flow, and
4. A coagulant is present in both clarifiers.

The rule language also indicates that the coagulant may be excess lime or magnesium hydroxide. This list of conditions is sound and appropriate assuming that the demonstration of performance provisions of the proposal are workable in the final rule, so that utilities that only employ single-stage softening are afforded an opportunity to demonstrate greater removals than the assumed 3-log equivalent to conventional coagulation-flocculation-filtration. It would be helpful if the table in §141.722 could be rewritten to parallel this text. The proposal text in the table calls for "coagulant addition" only; alternative text might be "coagulant (i.e., alum, ferric chloride, lime, or magnesium hydroxide, etc.)."

[57] Cornwell, D., M. MacPhee, R. Brown, and S. Via. 2003. Demonstrating *Cryptosporidium* Removal using Spore Monitoring at Lime Softening Plants. Jour. AWWA. 95:5:124.

Response to Requests for Comment, 68 FR 47697 §IV(C)(7)(c)

The agency requests comment on the following issues concerning softening on page 47697 of the proposed rule:

Request for Comment

Whether the information and analyses presented in this proposal supports an additional 0.5-log credit for two-stage softening, and the associated criteria necessary for credit.

Response

EPA has appropriately and accurately summarized the available literature. Available data indicate that a typical single-stage softening processes routinely provides as much or more *Cryptosporidium* removal as traditional coagulation-clarification- filtration treatment processes. Consequently, drinking water treatment plants that practice lime softening should achieve an average 3-log removal of *Cryptosporidium*, as was assumed for other clarification and filtration treatment ("conventional") plants in the Bin Requirements Table of the Stage 2 M/DBP Agreement in Principle. When a secondary clarification step is included in a treatment process, such as with two-stage softening, available data suggest that the second clarification step provides increased redundancy and stability to the treatment train. It also provides an additional treatment barrier to the passage of protozoa into the potable water supply. Consequently, an additional 0.5-log credit is appropriate for two-stage softening and other plant designs that employ multiple, continuously operated, clarification processes in series.

Comments on Guidance Manual

EPA provided a Draft LT2ESWTR Toolbox Guidance Manual for review with the LT2ESWTR. AWWA considered both the regulatory language and associated guidance in drafting its comments. AWWA recommends that EPA respond to the comments in this section, as well as Section 4.1.1, by revising Chapter 5 of that Guidance manual.

4.2.9 Demonstration of Performance

As noted previously, data and discussion by EPA in the LT2ESWTR and associated guidance manuals does not properly represent the true *Cryptosporidium* removal capabilities of existing surface water treatment systems that are in compliance with the IESWTR. An important inaccuracy in the EPA evaluation is that data were included that were not representative of IESWTR compliant water treatment plants due to the researchers operating the process in a "non-optimized" mode. EPA is not alone in erroneously characterizing the available data, as this mistake was not immediately identified in AWWA's initial analyses. AWWA has found that re-evaluation of data published both before and after the IESWTR reveals that conventional clarification plus a filtration system operated under conditions representative of compliance with the IESWTR or LT1ESWTR (turbidity $\leq$0.3 NTU) produces a mean and median *Cryptosporidium* removal of 4 to 6 logs.[58] In fact, the actual removal capabilities of these systems may be even greater because the filtered water *Cryptosporidium* concentrations were typically below detection limits in these studies. With the inclusion of data not representative of IESWTR compliance in the analysis, the evaluation underestimates the true *Cryptosporidium* protection potential of existing facilities that are in compliance with the IESWTR.

[58] EET, LT2ESWTR Treatment Requirements *Cryptosporidium* Monitoring, Bin Assignment, Core Treatment, And Microbial Toolbox, 2003

This does not mean that the automatic 3.0-log credit for a single clarification and filtration process should be increased to an automatic 4.0-log credit or higher, but it does point out that, consistent with the literature, many existing, well-run surface water treatment plants will be able to provide 4.0-log or greater *Cryptosporidium* removal. The Stage 2 M/DBP FACA recognized this and included "demonstration of performance" in the microbial toolbox recommendation to accommodate such cases.

Penalizes Facilities Attempting DOP Studies

A provision in the rule proposal (section IV.C.17) and in Chapter 12 of the Microbial Toolbox Guidance Manual allows states the discretion to penalize facilities that conduct a DOP study and end up mathematically demonstrating a total credit that is less than the automatic credits allowed by LT2ESWTR. For example, a state can choose to award a 3.3-log credit to a facility that qualifies for 3.5-log automatic credit if the utility was only able to mathematically demonstrate 3.3-log removal in a DOP spore study or pilot study. Inclusion of this penalty will deter facilities that may have benefited from using the credit from even trying for the credit.

AWWA believes that this DOP penalty provision is misguided and inconsistent with the practice and science of drinking water treatment plant design. Pilot-scale and full-scale testing is routinely used to demonstrate treatment systems and treatment system modifications to primacy agencies. Because of the conservative nature of these study designs and the implementation challenges which any individual pilot or full-scale study may encounter, primacy agencies do not as a matter of practice impose lower removal credit under the SWTR as a result of a site-specific study. Drinking water utilities, their consultants, and primacy agencies generally accept that full-scale treatment plants perform better than pilot plants. AWWA believes this provision should be removed entirely from the proposal and associated guidance.

In the event that the agency imposes this penalty provision within the DOP guidance, this provision should be accompanied by a set of qualifying tests so that individual utilities are not penalized by poorly designed or operated tests. Test results would need to withstand scrutiny with respect to:

1. The conservative nature posed by the selected surrogate vs. *Cryptosporidium* oocysts,
2. Demonstration of adequate surrogate in the influent water,
3. Demonstration that the laboratory analysis was not flawed,
4. Demonstration that the pilot test was operated correctly and within the appropriate testing regime, and
5. The better performance achieved by full-scale treatment plants.

Full-Scale Studies Using Aerobic Spores

Full-scale studies using aerobic spores are an appropriate test strategy for determining removal credit through DOP. A full-scale test should entail one year of weekly, full-scale aerobic spore monitoring data because:

1. Aerobic spore removal is a conservative indicator of *Cryptosporidium* removal;
2. Approved analytical methods are available for aerobic spores using equipment, materials, and procedures that are familiar and available to drinking water microbial laboratories;
3. Using larger samples volumes lowers the finished water detection limits for spores and this will increase the ability to mathematically demonstrate higher credits (lower detection limits can underestimate true treatment capability of system);
4. Use of mean to calculate the numerical value of the DOP credit will either result in gross miscalculation of the true spore removal (can be over- or under-estimated) or will require complicated statistical methods to identify and correct data outliers and account for censored (BDL) data. Use of median spore concentration data avoid these problems, and will result in a suitable and simpler approach to establishing the numerical value of the DOP credit;
5. Low raw water spore occurrence can inhibit ability to mathematically demonstrate true treatment capability of systems being evaluated and will limit the ability of some plants to use a full-scale DOP study to obtain approval for additional credit;
6. Facilities using at least one year of weekly full-scale spore monitoring data can demonstrate 4.0-log or greater spore removal, and hence are capable of achieving at least the same level or higher of *Cryptosporidium* removal; and
7. Collecting spore samples more than once per week is not necessary to establish the DOP credit (though facilities may voluntarily choose to collect samples more often).

Pilot-Scale Studies

A DOP pilot-scale challenge study would involve measuring removal of spiked *Cryptosporidium* or appropriate surrogate in a minimum 2 to 5 gpm pilot facility mimicking the full-scale treatment plant. Source water for the pilot facility should be provided from the location representative of where the *Cryptosporidium* bin assignment samples are/were collected. Although explicit guidance on pilot studies is not available from USEPA, the following would be reasonable for most facilities:

1. Challenge studies should be conducted on a frequency and duration discussed with and approved by the primacy agency. The procurement of sufficient volumes of spores or *Cryptosporidium* to spike influent water for long periods of pilot operation is problematic and may not be possible. Rather than requiring extensive piloting duration, pilot protocol schedules should take into account operating conditions such as spring runoff turbidity increases and cold water impacts to ensure that pilot results provide a robust representation of treatment challenge conditions. In some cases, a two-week challenge study may be sufficient, while in other cases, two weeks per quarter may be needed;
2. The study should be preceded by two weeks of side-by-side studies comparing performance of full-scale facility to pilot plant operated under identical conditions

(it must be shown that full-scale performance equals or exceeds pilot-scale performance through the final filtration stage);

3. Monitoring of raw, spiked, and finished water grab samples to include turbidity, particle counts, and *Cryptosporidium* (or other microbial indicator);
4. On-line, continuous turbidity monitoring of individual filter and combined filter effluent is recommended. On-line continuous particle count monitoring may be included for evaluating operations of the pilot facility, but this monitoring should not be a requirement or condition for the credit;
5. Pilot-study protocol to be negotiated with and approved by the primacy agency;
6. Objectives of testing should be to establish performance under routine or typical conditions (not "worst-case" scenarios – see later discussion), with "typical" performance established by monitoring removal of *Cryptosporidium* (or approved surrogate) in combined filter effluent (not in individual filters – see discussion below); and
7. DOP credit established in pilot studies will be applicable to full-scale plant at full-scale flow rates consistent with unit process loading rates used in pilot-scale unit processes (flocculation, clarification, filtration) during DOP evaluation, unless otherwise negotiated with the state.

This proposal departs significantly from Chapter 12 of the draft Microbial Toolbox Guidance Manual, which outlines an approach that is much more extensive than is routinely applied in approval of drinking water treatment plant design and modification. For example, Chapter 12 reflects 52 weeks of testing (Table 12.3, page 12-13 of draft Microbial Toolbox Guidance Manual), a requirement that is 12 – 25 times more extensive than currently required for other similar applications of special study testing.

The objective of testing should be to represent performance under routine or typical conditions, not necessarily the "worst-case" conditions emphasized in the draft guidance manual. This is consistent with the goal and framework of the LT2ESWTR, which is intended to address endemic risk of cryptosporidiosis associated with average source water *Cryptosporidium* challenges, assuming performance consistent with IESWTR (or LT1) requirements. In addition, "typical" treatment performance is reflected by measuring removal performance between raw (plus spike) through combined filter effluent, not between raw water and individual pilot filters. This is consistent with the requirements for the DOP credit using spores and with Section 12.5.2.1 of the guidance manual. However, Table 12.3 of the guidance manual introduces confusion on this point by implying that sampling must be conducted at individual filter effluents.

The DOP credit established in pilot studies should be applicable to the full-scale plant at full-scale flow rates consistent with unit process loading rates used in pilot-scale unit processes (flocculation, clarification, filtration) during the DOP evaluation, unless otherwise negotiated with the primacy agency. For example, a pilot study achieves >4.5-log removal of *Cryptosporidium*, using the primacy agency approved protocol, when pilot filters were operated at 8 gpm/sf. In this example, the full-scale plant should be certified for a total credit of at least

4.5-log, not the 3.0-log automatic credit, as long as the full-scale plant filtration rate is <8 gpm/sf. This does not mean the primacy agency is required to certify the full-scale plant for filtration rates up to 8 gpm/sf. However, it does mean that as long as the primacy agency establishes the maximum filtration rate for the plant anywhere below 8 gpm/sf (e.g., 4.5 gpm/sf), the primacy agency can not award a credit lower than 4.5-log.

Appendix 1 includes a complete description of a pilot and full-scale DOP study. Also, once established, the DOP credit should be retained as long as the facility maintains compliance with the IESWTR and there are no major changes made to the treatment processes.

4.2.10 Membranes

In reviewing the microbial toolbox, AWWA is concerned that the agency is not holding all technologies to equivalent compliance requirements. Compliance determinations should be consistent across different treatment technologies. For example, membrane modules and racks are akin to UV reactor and banks, which are not unlike ozone contactors. The compliance requirements for various treatment technologies should be consistent in the application of safety factors employed for design, the allowable off-specification water released downstream of the treatment, whether compliance is based on observations per unit time or per unit volume, and the use of hourly, daily, monthly, or annual performance metrics. The agency should review the membrane provisions with this consideration in mind.

4.2.11 UV

Inactivation using ultraviolet light (UV) is the low-cost compliance technology for the LT2ESWTR for utilities in Bins 3 and 4. UV will also be used by many utilities as a proactive measure and as an additional treatment barrier. Therefore, feasibility of UV under the proposed validation and operation protocols is especially critical for successful rule implementation. The availability of UV is a "fundamental premise" of the Agreement in Principle (§5.3). AWWA believes that UV Disinfection Guidance Manual needs to be much clearer in order to meet the proposed regulatory requirements on a national scale. AWWA's main concerns are outlined below.

Generic Application of UV Disinfection Guidance

The purpose of the UV Disinfection Guidance Manual as envisioned by the Stage 2 M/DBP FACA was to facilitate implementation of UV on a national scale. The FACA discussed several principles:

1. Identifying information needed to ensure that utilities could obtain apples-to-apples comparisons among different reactor designs;
2. Facilitating primacy agency approval of UV systems;
3. Educating the "average" drinking water system design engineer who is not as familiar with designing UV systems as clarification systems, filters, membranes, etc.; and
4. Informing water treatment plant operators about operational issues related to UV systems.

While the draft guidance manual has made significant progress toward three of these four objectives, the draft may not facilitate primacy agency approval of UV systems, at least, not with any sense of national consistency. In promulgating the LT2ESWTR and Stage 2 DBPR, the agency is assuming that UV will be a readily available treatment technology throughout the United States. At present, the draft UV Disinfection Guidance Manual is presenting UV disinfection in a manner that may not lead primacy agencies to form technically sound policies on UV that will allow its practical and timely adoption by the drinking water utility community. The requirements may not result in consistent implementation among the various primacy agencies. In particular, EPA should encourage primacy agencies to:

1. Accept results of validation testing per guidance manual or other EPA accepted protocol, and
2. Use the ranges of validations and supporting CFD analysis to approve reactors and "dose" for individual water treatment plants within the parameters tested without additional testing by the utility.

UV System Design

EPA is engaged in preparing three regulatory actions that will increase the installation of UV at individual drinking water utilities (i.e., the LT2ESWTR, the Stage 2 DBPR, and the Groundwater Rule [GWR]). The UV Disinfection Guidance Manual provides information that assists these utilities in considering UV disinfection, but EPA needs to ensure that its guidance does not potentially impose a national design "straight jacket." For example, the heavily structured validation process in Germany has allowed UV implementation, but UV manufacturers and consultants indicate that such an approach severely limits innovation in reactor design and operation.[59]

EPA has a considerable reservoir of UV expertise at its disposal, but information is limited about the site-specific circumstances for retrofits or greenfield designs at the hundreds of individual water treatment facilities that will install UV to comply with the LT2ESWTR. Therefore, the agency's guidance should be limited to the factors that should be considered in the design of an UV system and the provision of practical examples. EPA should not be engaged in setting a *de facto* national design standard. For example, the draft guidance manual recommends hydraulic conditions of straight pipe for 10 pipe diameters upstream and 5 pipe diameters downstream. This many not be possible for validation and installation in existing, tight filter galleries. As another example, the draft guidance manual strongly discourages post-clearwell UV installations. While post-clearwell installations present significant challenges, installation of UV between the filters and the clearwell may be inappropriate or infeasible in certain circumstances. If EPA severely discourages post-clearwell installation in its guidance, during actual permitting by primacy agencies, this "advice" will become a *de facto* prohibition.

UV Dose Table

The UV dose table in §141.729(d)(2) encompasses dose requirements for inactivation between 0.5-log and 4.0-log inactivation of *Cryptosporidium*, *Giardia lamblia*, and virus. Developing

[59] UV Stakeholder Meeting, Dec 7-9, 2003, Washington DC, AWWA.

these dose tables has been challenging. Even with a large amount of data on UV inactivation, the available data are frequently flawed with respect to several factors, including:

> Censored Data - Censored data are data for which an analytical endpoint was not reached. With respect to UV, the inactivation achieved during the experiment was greater than the upper limit that could be demonstrated by the analytical method. For instance, where the upper limit was 2-log, and a result of >2-log is given. Use of such data in any statistical analysis discounts the actual effect of UV, when in fact, the value is a result of inadequate methodology.
>
> Tailing - A drop in inactivation at higher disinfecting doses indicates incomplete delivery of the disinfecting agent. Tailing is generally an artifact of the laboratory technique and under-estimates the response of the organism to the disinfecting agent.
>
> Peer review – Peer review either through publication or through review by a panel of unbiased experts is an important milestone in the selection of data dose table development. Such scrutiny, even of well-qualified researchers, may reveal concerns or modify conclusions of scientific studies.

Data that are censored, data that demonstrate tailing, and data that lack peer review are reflected in the doses included in §141.729(d)(2).[60,61] These three factors consistently weight the analysis toward higher, more conservative dose values. With respect to censored data, EPA employs Bayesian statistical analysis as a means of compensating for censored data (i.e., $I(C_{ijk})$) in the analysis of *Cryptosporidium* and *Giardia lamblia*.[62] In using this Bayesian algorithm, EPA employs an analytical approach that would provide a good estimate of the actual log inactivation assuming the true value were not much greater than the censoring limit (i.e. the highest measurable value). However this assumption is unlikely to hold, because these experiments employed very high doses due to the expectation that UV would not be an effective disinfectant agent for protozoa. Consequently, the approach is a very conservative estimate of the potential log inactivation because the statistical algorithm generates a conservative estimate of the censored observations.

Tailing is a function of the actual data available and the experimental design for the study that produced the data. Appendix B of the UV Disinfection Guidance Manual that EPA's analysis does not appear to compensate for the tailing observed in the UV data at higher UV doses.

AWWA does not contest the *Cryptosporidium* and *Giardia lamblia* UV dose model or the resulting values in the UV dose table. The UV dose table has a built-in safety margin because entries correspond to lower bounds of the "credible range" derived from inactivation study data. AWWA is seriously concerned that additional layers of safety factors related to design criteria and redundancy requirements specified in guidance result in excessive conservativism in UV

[60] Ultraviolet Disinfection Guidance Manual, Appendix B. Derivation of UV Dose-Response Requirements, 2003.
[61] EPA does employ a data quality check internal to its analysis that screens some data out of the statistical analysis underlying the UV dose table.
[62] Ultraviolet Disinfection Guidance Manual, Appendix B. Derivation of UV Dose-Response Requirements, 2003, B-10.

application requirements. Furthermore, utilities will want to operate with a margin of safety relative to regulatory requirements.

AWWA encourages EPA to develop an approach to UV disinfection that is akin to the approach that is employed for other disinfectants such as chlorine or ozone under the SWTR. The SWTR rule specifies:

1. CT table, and
2. Basic compliance metric appropriate for identifying situations warranting state intervention and public notice.

Additional direction was provided through guidance, namely:

1. Basic T_{10} calculation of contactor hydraulic residence time for calculation of time in the CT equation;
2. Approaches to integrating disinfectant contact time throughout the water treatment plant; and
3. Option for site-specific studies to address site-specific circumstances.

Individual states have expanded on this basic model within their primacy authority, but the national framework set in 1989 is substantially the same nationwide. Individual utilities apply disinfectant per utility-specific Standard Operating Procedures (SOPs) that include appropriate alarms and safety factors to ensure CT is consistently and reliably achieved.

Extend UV Dose Table to 5.0-Log Inactivation

EPA should continue the UV dose table for *Cryptosporidium*, *Giardia lamblia*, and viruses to 5-log inactivation. Appendix B of the UV Disinfection Guidance Manual indicates that the data used to model the range of inactivation represented in the current dose table includes experimental data demonstrating greater than 5-log inactivation for *Cryptosporidium* and viruses. Experimental data also demonstrates greater than 4.5-log inactivation of *Giardia lamblia*. Moreover, the conservative nature of the statistical approach applied is clearly demonstrated graphically in Figures B.4 – B.6 (*Cryptosporidium*, *Giardia lamblia*, and viruses respectively). The agency's model estimates a 5-log inactivation level would be almost four times the required 3-log UV dose for *Cryptosporidium*. The percentage increase would be substantially smaller for viruses, but the levels of inactivation required for the adenovirus model organism are a conservative indicator of inactivation required and consistently involve very high UV doses.

Adenovirus as an Indicator

Under the LT2ESWTR, most surface water systems will consider UV disinfection for inactivation of *Cryptosporidium* and *Guardia lamblia*, not viruses. The very high UV doses included in §141.729(d)(2) for viruses make maintaining SWTR virus CT compliance with free chlorine a more economical and practical solution. These doses will also be a critical part of the GWR implementation. Under the GWR, groundwater systems that are required to disinfect will be required to provide 4-log virus reduction and UV was identified in the proposed rule as a viable compliance technology. The use of adenovirus as a conservative indicator of virus inactivation substantially increases the required UV dose over previous estimates. Moreover, EPA's LT2ESWTR preamble and the UV Disinfection Guidance Document do not articulate:

1. How EPA arrived at its decision to employ adenovirus as a conservative indictor of virus inactivation by UV;
2. What other options the agency considered in selecting adenovirus; and
3. How the conservatism implicit in the use of adenovirus to identify UV inactivation requirements compares to the use of other surrogates (e.g., Hepatitis A to set SWTR virus inactivation requirements).

AWWA encourages the agency to consider whether the occurrence of more UV-sensitive waterborne viral pathogens, relative to the occurrence of adenovirus, should be taken into account in assigning dose requirements for viruses. Adenovirus is principally a respiratory pathogen while other viruses like rotavirus, hepatitis, and poliovirus are more likely to be waterborne. The latter organisms tend to require 20-40 mJ/cm^2 for 4-log inactivation, an order of magnitude lower than the 186 mJ/cm^2 UV dose table requirement for adenovirus.

Outstanding Issues with UV Dose Tables

The UV dose table in §141.729 is the regulatory requirement and the benchmark for compliance. As currently written, the UV Guidance generates a substantially different UV dose table (Tier 1) that is a de facto regulatory requirement over and above the UV dose table in §141.729. The dose table in the UV Guidance Manual is substantially (three to four times) greater than the regulatory requirement due to the safety factors imposed through guidance. This situation creates two significant concerns:

1. A UV dose table in regulation when compliance values are located in guidance creates confusion; and
2. The UV dose table in §141.729 reflects a factor of safety of two to three times the dose actually required to cause the desired level of inactivation.[63] The Guidance manual adds another safety factor of two to three times. The net result is a dose requirement of four to nine times what is actually required to achieve inactivation of *Cryptosporidium* or *Giardia lamblia*.

AWWA recommends that EPA finalize a UV dose table in the rule language similar to the dose table in the proposed rule. This dose table should only reflect available collimated beam inactivation study data. Achieving this dose is the objective for those PWSs employing UV disinfection. Guidance should entail a single decision-making process that reflects key design parameters associated with reactor design and installation. This process should parallel determination of dose and contact time for a chemical disinfectant and should result in a site-specific "applied" UV dose necessary to ensure reliably achieving the required UV dose in the rule. This process should address each of the uncertainties currently reflected in the Tier 2 process. This decision-making process should be supported by a spreadsheet that allows the

[63] Ultraviolet Disinfection Guidance Manual, Appendix B. Derivation of UV Dose-Response Requirements, 2003, B-16, Describes use of lower bound 80% "credible interval" on model regression to derive UV requirements.

selection of default values when installation-specific knowledge is not available. To the extent possible, this process should separate considerations associated with the reactor from those particular to a given installation. Such separation will allow the development of supporting data by UV manufacturers and third party validation facilities.

Excessive Safety Factors

In the final guidance manual, the agency must pay special attention to operation and maintenance (O&M) costs, particularly power costs. Power costs are essentially proportional to UV dose. Use of excessive safety factors will result in higher O&M costs for utilities. In addition, the ability to ramp the UV dose up and down in response to water quality, flow rate, and reactor conditions is key to optimizing power usage.

Power consumption is a very real practical concern that has direct implications for the ongoing affordability of UV operations. Eliminating operational flexibility is also a very real concern with the guidance manual. As a consequence, UV systems will have to be significantly over designed to allow utilities to routinely operate with some margin for error with respect to regulatory requirements. As violations and/or public notice requirements should only be applicable when there is a credible public health concern, additional consideration should be given to the stringency of the proposed UV Disinfection Guidance Manual.

Tier 1 Requirements

The Tier 1 requirements are, as AWWA understands them, intended to provide a streamlined approach to approval of a UV reactor. Safety factors are introduced that, in combination, result in a conservative estimate of delivered UV dose that is well in excess of primacy agency expectations for design conservatism. While AWWA questions the level of conservatism imposed through the Tier 1 requirements, another practical point EPA should be aware of is that the information needed to comply with the Tier 1 requirements is not generally available. Some examples include variability in lamp output and uncertainty in accuracy of some types of flow meters. Requiring data not generally available from manufacturers -- as it is not important to the actual design of the equipment or compliance with standards bodies -- illustrates an overly complex level of evaluation that is beyond what is needed to ensure LT2ESWTR compliance.

AWWA, through CH2M Hill, conducted an example Tier 1 analysis of an existing low-pressure lamp UV installation. The report from that comparison is attached in Appendix 8. In summary, this review found that current Tier 1 criteria are in excess or different from standard engineering practice in several respects. The following Tier 1 criteria that were not met in this analysis included: sensor location; NIST traceable sensor standard and sensor uncertainty; lamp variability; and confidence intervals on dose. The review also identified a number of other validation requirements included in guidance that are unclear with respect to compliance expectations. Examples include evaluation of lamp and sleeve aging, adherence to QA/QC sample enumeration, inclusion of low-UVT/high-power and high-UVT/low-power test points, and UV intensity sensor evaluation. We discuss specific modifications to the Tier 1 protocol recommended in the review in the Appendix.

The agency should remove the Tier 1 appraisal from the final guidance document per the previous recommendation. The Tier 1 appraisal currently provides a useful starting point for the development of default assumptions included in the single decision-making process described above.

Reactor Validation

Three issues of concern are validation of reactors, the follow-up approval of validation by the primacy agency, and the requirements for third-party validation. The guidance is based on low-pressure (LP) lamps, viruses as challenge organisms, and use of a validation test facility. The guidance should, and does allow validation at varying flow rates, UV transmittance (UVT), reactor/piping configuration, and lamp characteristics. To simplify approval, primacy agencies should be strongly encouraged to accept results of validation testing from a test facility, other operating sites, or using another EPA accepted protocol. The question remains as to what qualifies as third-party validation given the realities of how validations are being completed.

Off-Specification Water

The proposed LT2ESWTR states that unfiltered water supplies using UV are expected to provide inactivation to 95% of the water delivered each month. A similar provision is absent for filtered systems. The draft guidance manual alludes to filtered systems being expected to meet a significantly higher, but undefined, reliability factor. The allusion to this higher, but undefined, reliability factor should be eliminated to minimize confusion. Filtered systems need more explicit details in the final guidance manual on this reliability factor. This factor would apply when power supply is lost for a short period, as well as to any “off spec” water resulting from lamp fouling, reduced UVT, etc.

The proposed requirements for design of UV systems are extremely conservative. The 95% off-spec criteria for unfiltered systems is not gauged to failure to meet the delivered UV dose but to failure to meet validated conditions that reflect numerous safety factors which together increase the required dose three- to four-fold. AWWA recommends that an off-spec performance standard for filtered systems measured on a monthly basis should be 90% (i.e., 90% of finished water should be within specifications as described in guidance manual). EPA should evaluate setting the unfiltered off-spec criteria at the same level as is employed for filtered systems.

Because monitoring of UV systems will be virtually continuous and accomplished at the individual reactor level rather than for the entire treatment train, off-spec requirements should be determined based on volume (i.e., volume treated) and not time (i.e., hours of operation). Current federal requirements for monitoring and reporting of chemical disinfection are based on hours of operation, so this last recommendation is a departure from previous rule structures. Current rules for ozone are, however, a useful model for bridging this gap between UV and chemical disinfection. Previous federal regulations provide good models for UV regulatory requirements. In particular, regulation of ozone specifies a single measurement each day under peak flow for determination of compliance with CT. Individual states specify different mechanisms for ensuring that this observation is appropriately captured. For UV, federal regulations can specify a similar daily compliance observation that would determine compliance with the MCL. Federal guidance could address off-spec level goals and tracking in the context of operational monitoring and reporting to the state, much like individual filter monitoring and reporting.

The guidance manual does not differentiate between off-spec water and down time. These two operating conditions are significantly different and the guidance manual should address these differences. Down time would be defined as when the entire UV system is not operating, while off-spec would be defined as when the system is operating but not meeting the required UV dose. Off-spec operation will still provide some level of inactivation and likely a high level due to the multiple safety factors. The guidance manual should provide methods of calculating both types of operating scenarios and build both types into the compliance calculations.

The guidance manual discusses uninterrupted power supplies (UPS) and back up power as necessary to ensure system reliability. AWWA believes dual power feeds and/or back up power supply are important to ensure reliability. UPS is estimated to increase the cost of UV by 5% to 10% for each installation. An ongoing AwwaRF project is specifically addressing power supply issues surrounding UV disinfection. This project will be completed prior to the promulgation of the final LT2ESWTR and EPA should incorporate it into the final guidance manual.[64]

Maintaining "Validated Conditions" Over Time

Over the life of the UV system, ongoing operations and maintenance of the UV system will necessarily lead to changes in the components in the UV reactor and monitoring system. Changes will stem from equipment design life, component failure, planned obsolescence in manufacturer inventory, and technological advances. Such changes will range from changing lamps and sensors to updating monitoring software and even replacing reactors. Some activities in this spectrum clearly do not warrant revalidation.

Changing reactors would clearly necessitate interaction with the primacy agency and presentation of information about the new reactor. However, the replacement of lamps, sensors, software, and other routine maintenance activities associated with UV operation should not automatically trigger revalidation and interaction with the primacy agencies. In these instances, the utility has an obligation to review the specifications for the relevant component of the UV system, comparing those specifications to those of the replacement component. Where the replacement component is compatible and equal to or superior to the initial validated system component specifications, then the use of an alternate component (even components by a different manufacturer) is appropriate. Maintenance records should be kept to document this type of comparison and such records should be available for the primacy agency to review, if it so chooses, during its regular sanitary survey inspection.

New UV Technology Acceptance

The UV Disinfection Guidance Manual is written based on low-pressure UV lamps and physical testing experience at the Portland UV Test Facility operated by Carollo Engineers. Austria, Germany, and New York State also operate testing facilities. Individual manufacturers have in-house testing facilities as well. NSF is also revising its protocols to support validation of UV reactors for LT2ESWTR application. Reactors will be validated and installed throughout the country. The UV Disinfection Guidance Manual needs to provide a level playing field (i.e., data from any facility performing validation tests that conform with the guidance manual should be

[64] AwwaRF #2861, Integrating UV Disinfection Into Existing Water Treatment Plants

accepted) for all of these facilities to validate UV reactors and provide clear expectations for validation studies so that utilities obtain information that is usable, meaningful, and comparable. The guidance manual also needs to maximize the potential for primacy agencies to accept validation work performed in other states or countries.

The draft guidance does not presently provide a level playing field across available UV technologies. The draft guidance penalizes medium-pressure UV lamp systems due to handling of polychromatic bias. Polychromatic systems are required to have a 20% higher dose than monochromatic systems. The proposed approach to polychromatic bias in Section 4 and Appendix C of the guidance does not reflect the full impact of polychromatic spectra on *Cryptosporidium* oocysts. Consequently, the draft guidance requires greater UV dosage from UV systems that employ medium pressure lamps than from systems that employ low-pressure lamps.

The manual needs to recognize that UV disinfection is a rapidly evolving technology. Developments are under way on almost every aspect of UV, including technology that would:

1. Increase the efficiency of UV delivery,
2. Remove UV lamps from the water flow, and
3. Provide alternatives to mercury vapor lamps.

The draft guidance does not provide a realistic validation pathway for emerging technologies and thereby inhibits innovation that might provide important solutions to design and risk management issues that the current UV guidance is seeking to address.

Computational Fluid Dynamic Modeling

The draft UV Disinfection Guidance Manual suggests computational fluid dynamic modeling (CFD) as a method to analyze alternative piping configurations. This is an appropriate but limited recommendation. The guidance manual should encourage primacy agencies to accept the use of CFD models to approve reactors and "dose" for WTP that fit within the range of parameters tested during reactor validation and / or supplemental testing.

The draft guidance also includes disincentives to use CFD -- a very powerful design tool -- in addition to placing roadblocks to the development of new UV technologies. The guidance assigns a minimum 20% increase in UV dose due to uncertainty in CFD estimates.[65] The proposed criteria significantly increases the testing required to validate a UV reactor by implying a limited role for CFD and penalizing the use of CFD in a recognized application. Use of CFD models to interpolate, and possibly, extrapolate observed inactivation to flow, dose, and transmissivity conditions not specifically tested is essential to developing efficient and operationally robust UV system designs. The expense of reactor validations and the site-specific nature of some design factors make reliance solely on values observed in validation tests impractical.

[65] UV Disinfection Guidance Manual, page 4-10

The use of CFD in the design of UV reactors is already a standard industry practice. The draft guidance would in effect penalize utilities that employ reactors designed using state of the art design tools.[66] CFD has a clear role in validating variations in flow rates and piping layouts from the tested condition, after CFD has been shown to match the test condition. Any model generates an estimate reflecting the input parameters and some model estimates are more accurate than others. Therefore, model estimates are typically bounded by measures of statistical confidence. Which statistical measure is appropriate and the stringency imposed on a particular estimated value depends on the model and its application. The selection of a fixed percentage buffer on any CFD estimate is arbitrary and unsound.

The UV Disinfection Guidance Manual should promote the general acceptance of CFD to predict UV inactivation for reactors that are too large for a rigorous physical validation test protocol. Bioassay tests used to validate UV reactor performance at high flow rates (i.e., greater than 20 MGD) associated with testing very large reactors are both impractical and uneconomical. The logistical and practical difficulties associated with handling adequate quantities of test organisms and delivering sufficiently large volumes of water under controlled conditions to the test reactor essentially require the acceptance of CFD results.

Lamp Breakage

System isolation and quick valve closing are not practical solutions to lamp breakage due to water hammer and mechanical / hydraulic limitations. Breakage will result in small amounts of mercury release into water systems before automatic or manual systems can isolate the problem. In endorsing and encouraging UV as a disinfectant technology for drinking water, EPA must address this issue. The agency should:

1. Openly disclose the mercury exposure risk tradeoff and demonstrate that under realistic scenarios it presents a *de minimus* risk; and
2. Clearly articulate in the UV Disinfection Guidance Manual that the development of a site-specific mercury spill response plan that employs practical and prudent steps to minimize mercury releases is sufficient to reduce any risk associated with mercury to a *de minimus* level.

AWWA is genuinely concerned that, while the agency requests information about many of the proven and well-understood technologies being considered for LT2ESWTR compliance, the agency poses only a single question regarding the compliance technology the agency's own EA suggests will be the most frequently used by medium and large drinking water utilities.

Response to Requests for Comment, 68 FR 47713 §IV(C)(15)(c)

The agency requests comment on the following issues concerning softening on page 47697 of the proposed rule:

[66] Y.A. Lawryshyn and B. Cairns, UV disinfection of water: the need for UV reactor validation Water Supply Vol 3 No 4 pp 293–300,

Request for Comment
The agency requests comment on whether the criteria described in this section for awarding treatment credit for UV disinfection are appropriate, and whether additional criteria, or more specific criteria should be included. (68 FR 47713)

Response
AWWA has provided comment above on a number of issues that required attention in the UV Disinfection Guidance Manual. These recommendations speak directly to the appropriateness of the criteria for UV log-credit, in particular:

1. The UV dose table does not encompass an adequate range and should be extended to 5 log for *Cryptosporidium* and *Giardia lamblia*;
2. Basing the UV dose table for viruses on adenovirus is suspect and requires substantiation and reconsideration;
3. Potentially excessive safety factors are incorporated into the Tier 1 validation protocol;
4. Expectations for available data and resources required to achieve validation across the full range of a water treatment plant's operating conditions are inordinately and unjustifiably high;
5. The off-specification criteria are missing for filtered systems and should be set at an achievable level (95% percentile within specification is too stringent); and
6. The proposed criteria will stifle technological improvements in UV.

4.2.12 Ozone
AWWA believes that retention of ozone as a viable technology was an essential component of the Stage 2 DBPR Agreement in Principle. The following comments follow directly from this understanding of the Agreement in Principle.

Ozone is currently in use or in development at some of the largest water systems in the United States: Southern Nevada Water, Metropolitan Water District of Southern California, Tampa, Milwaukee, Seattle, Fairfax County (Va.) Water Authority, Dallas Water Utilities, and many other smaller communities. Systems are choosing ozone for a number of reasons, in addition to its ability to inactivate *Cryptosporidium*. As currently proposed, the ozone CT requirements are challenging, particularly in certain locales:

1. Coastal and arid regions where bromide levels are high in source waters with the potential for elevated bromate formation (keeping in mind that bromide levels during the ICR were lower due to higher than average rainfall); and
2. Northern and eastern U.S. where cold temperature inactivation requirements make reliance on ozone alone for high inactivation levels difficult.

While challenging, AWWA believes the proposed ozone provisions are substantially improved over the stakeholder draft. AWWA is generally supportive of the ozone provisions. AWWA has a number of detailed comments that will:

1. Clarify the requirements and inform implementation;
2. Facilitate practical implementation of ozone; and
3. Further enhance the viability of ozone, particularly with respect to balancing ozone application with bromate formation.

Balancing Inactivation and Bromate Formation

The Stage 2 M/DBP Agreement in Principle calls for retention of the current bromate MCL at 0.010 mg/L. This recommendation stemmed from the FACA's view that ozone should be available as a treatment technology for *Cryptosporidium* inactivation. The FACA recognized ozone as a valuable disinfectant that is more effective for some microorganisms than chlorine and other more-frequently used disinfectants. Also, the FACA recognized ozone was as an important oxidant to control taste and odor, destroy organic contaminants, and enhance performance of other treatment processes such as coagulation-flocculation-clarification processes. The FACA also considered the past or ongoing investment by a number of drinking water utilities in ozone disinfection as a proactive step to address either disinfection byproducts or *Cryptosporidium.* This recommendation is particularly significant given the agency's characterization of bromate health effects.

In the spirit of the FACA's interest in retaining ozone as a viable technology in developing the ozone CT requirements, the agency should recognize that increased inactivation requirements will increase bromate formation, other things being equal (von Gunten and Oliveras, 1998, Song et al., 1997). As the Stage 2 M/DBP FACA realized, ozone doses necessary to inactivate *Crytposporidium,* even low-to-average bromide levels can result in bromate levels near the Stage 1 MCL. Though bromate control strategies exist, each of them has limitations (see e.g. Williams et al., 2003; Buffle et al., 2003):

1. pH control is effective, but can require costly chemical addition to first acidify and then buffer the water post-ozonation;
2. A serious side effect of pH control in some waters can be a significant rise in TDS which represents a water quality concern for both residential and commercial customers;
3. Ammonia addition can be effective for bromate control, though more so at high pH (in contrast to pH control which employs low pHs);
4. Ammonia addition can result in a loss of disinfection credit due to the pH range employed, necessitating the introduction of additional disinfectant or larger contact basins[67]; and
5. Application of the "ammonia process" for bromate control may not be feasible in moderate-to-high TOC waters where the required initial chlorine addition step could yield unacceptable THM and/or HAA concentrations. The effectiveness of

[67] Williams et al., Evaluation of pH and Ammonia for Controlling Bromate During Cryptosporidium Disinfection, JAWWA vol. 95, p.82

this process has been well demonstrated in low TOC waters (Buffle and Von Gunten 2003).[68]

While these control strategies will work in some waters, engineering and/or cost issues constrain their application. Consequently, the agency should carefully balance the level of conservatism reflected in the analysis underlying the ozone CT tables with the potential formation of bromate.

CT Table Methodology

AWWA recommends that the CT table for ozone and chlorine dioxide be based upon an upper percentile confidence interval (e.g., 90th, 95th percentile) about a first order regression equation through the available inactivation data. AWWA supports the proposed CT table as a balance between approach seeking the best available science and development of a CT table that affords a consistent and simply applied safety factor to address outstanding policy concerns.

EPA's proposed approach provides a reasonably transparent methodology to appropriately partition experimental / analytical variability (i.e., experimental method, between individual mice in experimental protocols, ozone residual measurement, mice infectivity and excystation, true volume of sample fed to each mouse) from variability in the underlying inactivation coefficient (K_{10}) (i.e., variability in the oocyst resistance to disinfection and effect of natural water matrix on the inactivation process). The approach employed for ozone is also relevant to the second chemical disinfectant addressed by the LT2ESWTR -- chlorine dioxide. The agency should more clearly describe how the treatment of variability should be addressed in site-specific studies.

Conditions Encompassed in CT Table

Inactivation

The current CT tables are limited to a minimum of 0.5-log *Cryptosporidium* inactivation. Several utilities that have to meet a minimum 0.5-log inactivation of *Cryptosporidium* may achieve required inactivation levels using multiple disinfectants (e.g., ozone with chlorine dioxide). To allow this, the CT tables should be extended to log inactivation levels below 0.5-log. The minimum log inactivation listed in the CT tables should be 0.1-log, the likely minimum level a system would achieve with a single disinfectant. Utilizing a minimum log inactivation in the CT table below 0.5-log is justified because the CT values listed in the table were derived from mathematical models that were based on inactivation results starting from 0-log. Therefore, excluding log inactivation values between 0 and 0.5-log is not justified.

Water Temperature

The current CT tables are limited to a maximum water temperature of 25 ºC. Several systems treat waters with temperatures exceeding 25 ºC during the summer months. Figure 1 shows frequency distribution profiles of water temperature for the Harwood's Mill Reservoir used by the Newport News (Va.) Water Works, and for the Colorado River water treated by the City of Phoenix, AZ. The data show that water temperatures can reach 30 ºC or higher. AWWA recommends that the CT table be extended to a water temperature of 35 ºC. The inactivation

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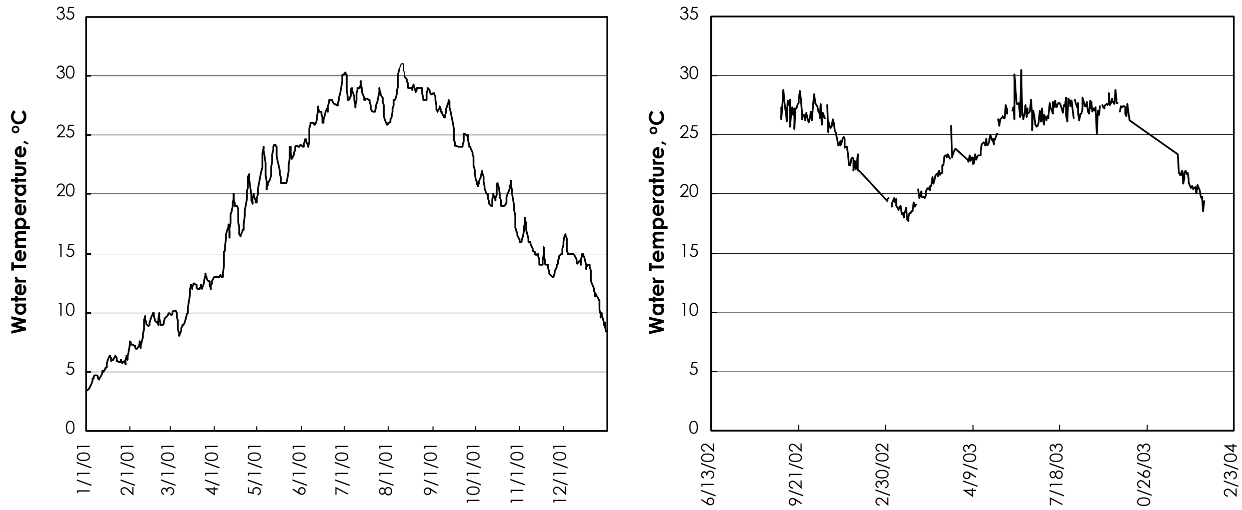
[68] M. Buffle and U. von Gunten. 2003. The Chlorine-Ammonia Process for Enhanced Bromate Minimization. In Proceedings of the American Water Works Water Quality Technology Conference. Philadelphia, AWWA

model used to develop the CT tables was based on a dataset that included various data points at 30 ºC and 37 ºC. Therefore, the confidence in the calculated CT values at the high temperatures should be as good as those at the low temperatures included in the current CT tables.

Figure 1. Temperature Profiles from Newport News, Va., and Tampa Bay, Fla.



Additional Information Needed in CT Table

The Guidance manual currently includes an equation to calculate the k_{10} values for the inactivation of *Cryptosporidium*, with ozone as a function of water temperature:

$$k_{10,Crypto.} = 0.0397 \times (1.09757)^{Temp}$$

This equation is important for water utilities because it can be incorporated into the plant's computer-control system. AWWA offers the following comments related to this equation:

1. In addition to the possibility of having to meet the inactivation requirements for *Cryptosporidium*, a plant is required to meet the inactivation requirements for *Giardia* and virus. Similar equations are needed for *Giardia* and virus. We propose the following equations for expressing the values of k_{10} for the inactivation of Giardia and virus with ozone:

$$k_{10,Giardia} = 1.022 \times (1.0750)^{Temp}$$

$$k_{10,virus} = 2.135 \times (1.0737)^{Temp}$$

   These equations were derived by fitting the k_{10} values as derived from the SWTR CT tables.

2. The equations are currently listed in Chapter 11 of the Toolbox Guidance Manual. These are not visible enough for primacy agencies and utilities to use. AWWA recommends that these equations be moved to the same page where the CT tables

are listed in the preamble and placed directly in the regulatory language. They can be listed in a separate table or in a footnote to the ozone CT table. However, we suggest modifying the equations to directly calculate the log inactivation values as a function of temperature and CT. The purpose of this change is only to simplify the understanding and application of these equations in plant control systems. The modified equations become as follows:

Microorganism	Suggested Equation for Rule
Cryptosporidium oocysts	$Log\ Inactivation = \left[0.0397 \times (1.09757)^{Temp}\right] \times CT$
Giardia cysts	$Log\ Inactivation = \left[1.022 \times (1.0750)^{Temp}\right] \times CT$
Viruses	$Log\ Inactivation = \left[2.135 \times (1.0737)^{Temp}\right] \times CT$

The regulatory language should state that the equations can be used to calculate the log inactivation of each microorganism down to 0.1-log, especially for *Cryptosporidium* inactivation with ozone.

Calculation of Compliance

Monitoring Period

Section §141.729(a) states that log inactivation is to be reported once per day during peak-flow hours. However, the Microbial Toolbox Guidance Manual recommends that hourly sampling be done if a utility does not know the hour of peak flow. The guidance manual requirement appears to be more stringent than the rule. Regardless, the hourly sampling requirement is unnecessary and will greatly increase the reporting burden on systems. Since several reporting requirements have a four-hour reporting period, EPA should revise the hourly requirement to a four-hour reporting period if a system cannot identify the hour of peak flow.

Conservatism in "C" Value

Table 11.3 in the Toolbox Guidance Manual recommends the use of C_{out} as the characteristic concentration, C^*, in reactive-flow chambers when using the T_{10} method. Considering that T_{10} is a conservative estimate of the true contact time through the chamber, and CT values are based on upper confidence limits, no additional conservatism is needed in the "C" value. AWWA recommends that the rule allow the use of the geometric mean (or log mean) of the influent and effluent ozone concentrations in reactive chambers:

$$C^* = \sqrt{C_{in} \times C_{out}}$$

Rationale for Criterion

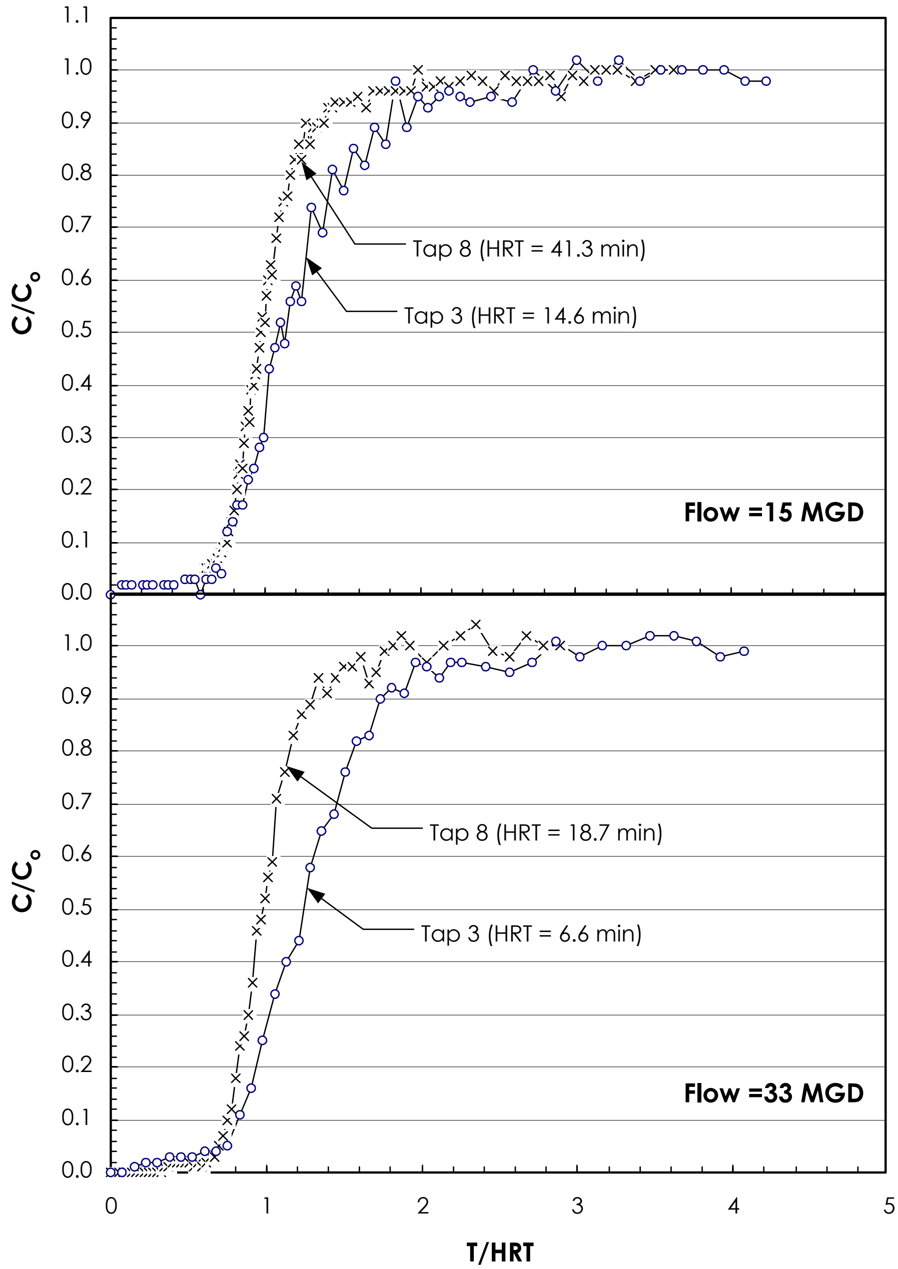
Page 11-8 of the current Toolbox Guidance Manual states that the T_{10} method "…cannot be used if the chambers with final concentrations of zero (non-detectable) are 50 percent or greater than the entire volume of the chambers." The rationale for this criterion is not indicated, and the document does not specify what a system should do if its ozone contactor operation falls within this criterion on a certain day. This requirement is an unnecessary complication not supported by scientific data. Figure 2 shows tracer testing results from and over-under contactor in Florida. The tracer tests were conducted at two flows: 15 and 33 MGD, and samples were collected from Tap 3 and Tap 8 along the contactor. Although Tap 3 is about one third the distance to Tap 8, the T_{10}/HRT values at both taps are virtually identical. The rationale is that the flow pattern develops through the first few chambers of the contactor and does not necessarily change through the rest of the contactor. A plug flow contactor with a 10-minute contact time has the same flow pattern as a plug flow contactor with a 20-minute contact time. With T_{10}/HRT ratios in ozone contactors in excess of 0.6, ozone contactors experience similar behavior.

The practical problem with the current limitation is the addition of an unnecessary layer of complexity to the operation of an ozone system. The uncertainty factors used in the calculation of T_{10}, C, and the log-inactivation value provide adequate safety factors. This additional burden is unwarranted.

Applying Multiple Compliance Algorithms

The Toolbox Guidance Manual indicates that a system can use either the T_{10} or the CSTR method in calculating the log-inactivation credit through ozone contactors, but systems "…should select one method to be used and use that method consistently". However, a system must meet several QA/QC criteria for every calculation of the log-inactivation credit. If a system fails a criterion on one day, it must be allowed to utilize the other method to calculate the log inactivation for the day. For example, if the ozone residual dissipates to below detection within less than 50% of the contactor, the guidance manual says that the T_{10} method cannot be used. In that situation, the system should be allowed to use the CSTR method to calculate the log inactivation. The guidance manual should explicitly state that a system may use the other method on specific occasions, when its pre-selected method is not applicable. Regardless of the reason for switching calculation methods, a system should be allowed to utilize any approved methodology on any day regardless of what it used on the previous day since there is no relationship between any two consecutive inactivation compliance reporting events.

Figure 2. Tracer Testing Results from an Over-Under Ozone Contactor in Florida



Using Average k* Value

The Extended-CSTR method uses a calculated ozone decay coefficient, k*, to calculate the log inactivation across an ozone contactor. The k* value is calculated as the average of two calculated k* values using three ozone residual measurements. However, the method includes a QC criterion of a maximum variance of 20% between the two individual calculated k* values and the average value. The current guidance manual states that if this QC criterion is not met, the average k* value cannot be used, and a system will need to re-sample the contactor and calculate a new k* value. Considering that inactivation is to be met 100% of the time, the rejection of the data based on this QC criterion and the requirement to resample is a high-risk requirement that many systems cannot take. AWWA recommends that USEPA change this requirement so that a system that fails the 20% QC criterion on k* can either resample and recalculate the k* value until it meets the QC criterion, or use the higher of the two k* values. Appendix 9 contains a memorandum documenting the need for an approach to k* in greater detail, providing datasets illustrating the issues involved, and proposing an alternative calculation when QC criterion is not met.

Determining the k_{10} Value

In determining the k_{10} value for the inactivation of *Cryptosporidium* with ozone, EPA staff determined the uncertainty factor to be applied to the regression line of $Ln(K_{10})$ vs. water temperature. The approach includes a rigorous statistical analysis to determine the relevant 90% confidence in the k_{10} value. Appendix A to the current Toolbox Guidance Manual includes a description of disinfection testing that a system may conduct to develop site-specific CT values. However, the document does not indicate how to calculate the uncertainty factor to apply to the regression line of $Ln(k_{10})$ vs. temperature. The statistical approach used in the development of the current CT table is recommended for use by individual systems for the development of site-specific CT tables. The approach includes the following steps:

Step 1 – Collect "n" number of pairs of CT and log-inactivation values at various temperatures

Step 2 – Divide each log-inactivation value by its corresponding CT value. This will provide a specific k_{10} value at a specific temperature

Step 3 – Plot all the $Ln(k_{10})$ values vs. water temperature. In this plot, "Y" is the $Ln(k_{10})$ value and "X" is the temperature

Step 4 – Utilize Equations 1 & 2 to calculate the upper (Y_U) and lower (Y_L) 90% confidence limits on the $Ln(k_{10})$ values. The only unknown in Equation 1 is the factor "*f*" which represents the fraction of the scatter that is attributed to variability in the microorganism itself and in the impact of the water matrix on the inactivation efficiency. In the development of the CT tables included in the rule, the value of "*f*" was determined to be 0.125. The value of "*f*" for the site-specific inactivation data collected by a utility can be determined by conducting a specific statistical analysis of the site-specific data gathered.

$$\left.\begin{matrix} Y_{U,j} \\ Y_{L,j} \end{matrix}\right\} = \hat{Y}_j \pm \sigma Z \left\{ f + \frac{1}{n} + \frac{\left(X_j - \overline{X}\right)^2}{\sum_{i=1}^{n}\left(X_i - \overline{X}\right)^2} \right\}^{0.5} \qquad (1)$$

where: X_i = x-value of the 'i' data point
$\overline{X}$ = mean x-value of all individual data points
$\hat{Y}_j$ = regression-line predicted value of Y for 'j' data point
$Y_{U,j}$ = Y value of the upper confidence limit at 'j' data point
$Y_{L,j}$ = Y value of the lower confidence limit at 'j' data point
n = number of data points
Z = single-sided probability distribution parameter
(Z = 1.2817 for 90% confidence limit)
f = Average fraction of error attributed to variability in the oocysts and the water matrix effect on inactivation efficiency
σ = standard deviation of the entire dataset, calculated using Equation 2.

$$\sigma = \left\{ \frac{\sum_{i=1}^{n}\left(Y_i - \hat{Y}_i\right)^2}{(n-2)} \right\}^{0.5} \qquad (2)$$

Segregated Flow Analysis

The ozone *Cryptosporidium* CT tables developed by EPA for LT2ESWTR are substantially higher than those required for virus or *Giardia lamblia* inactivation. Substantial cost consequences and potential health concerns (i.e., bromate formation) are associated with overly conservative application of ozone to achieve CT. Therefore, the further development of the Surface Water Treatment Rule concept of "segregated flow analysis" is critical to allow utilities to better estimate and manage the application of ozone for CT.

The Segmented (or Segregated) Flow Analysis (SFA) method for calculating log-inactivation through ozone contactors was considered by USEPA but was not included in the guidance manual because of concerns over accuracies of the method. Appropriate testing methods exist which a water system may conduct to evaluate the accuracy of the SFA method. AWWA recommends that the Guidance manual explicitly indicate that a system may conduct a study to demonstrate the SFA method to the state for use at its plant.

In addition, even if the state approves the application of the SFA method after a demonstration study, the description of the method application is not currently included in the guidance manual. AWWA recommends that the USEPA include an appendix to the guidance manual that details the application of the SFA method. In this manner, a state can utilize this appendix to approve the application of the SFA method after a system adequately demonstrates its accuracy. Appendix 10 provides a model approach to such a model guidance document.

Site-Specific Studies

In promulgating the SWTR in 1989, EPA introduced the concept of site-specific studies. AWWA supports the continuation of the application of this concept under the LT2ESWTR for *Cryptosporidium* inactivation. Utilities will have significant opportunities to refine the application of ozone at their facilities based on the above discussion of the ozone CT tables and methodologies to calculate ozone CT. Such efforts will require significant resources and are not investments that every utility will be able to undertake. However, when resources are available, so should the opportunity for site-specific studies.

Synergistic Inactivation

Synergistic inactivation is defined as the enhancement of the inactivation efficiency of a disinfectant against a certain microorganism by pre-exposing that microorganism to another disinfectant. This is defined as "synergistic inactivation" because the combined effect of the two disinfectants in series is greater than the added sum of their individual effects. Appendix 10 includes a memorandum prepared for AWWA analyzing the available data on synergistic inactivation of *Cryptosporidium* with ozone and chloramine, and recommending specific CT tables for the inactivation achieved by chloramine application downstream of ozone. The analysis presented in Appendix 11 clearly shows that achieving *Cryptosporidium* inactivation with chloramine is feasible downstream of ozone. Meeting target *Cryptosporidium* inactivation requirements with synergistic inactivation of ozone and chloramines, or ozone and chlorine, will greatly benefit water utilities, especially those limited in their ability to add ozone due to potential bromate formation.

AWWA recommends that the agency give serious consideration to reflecting synergistic inactivation in the LT2ESWTR with respect to ozone followed by chloramines and ozone followed by chlorine. Incorporating synergistic inactivation into practice would be most easily achieved through inclusion of CT tables, such as those included in Appendix 10 in the regulatory text, though application could be accomplished through guidance provisions that clearly indicate that the agency endorses the concept.

4.2.13 Chlorine Dioxide

As noted above, AWWA believes that the CT table for ozone and chlorine dioxide should be based upon an upper-percentile confidence interval (e.g., 90th, 95th percentile) about a first-order regression equation through the available inactivation data. AWWA understands and supports the proposed CT table as a balance between the best-available science and development of a CT table that affords a consistent and simply applied safety factor to address outstanding policy concerns.

Transfer of Ozone CT Approach to Chlorine Dioxide

While the guidance manual currently includes equations to calculate the k_{10} value for the inactivation of *Cryptosporidium*, no such equation is provided for chlorine dioxide. The inclusion of such equations for the inactivation of *Cryptosporidium*, *Giardia*, and virus with chlorine dioxide would be very helpful to utilities. Such equations are easily developed using the same approach used to develop the equations for ozone. Based on a similar approach, the following equation is proposed for the inactivation of *Cryptosporidium* with chlorine dioxide:

$$\text{Log Inactivation} = [0.001506 \times (1.09116)^{Temp}] \times CT$$

Using equations to calculate the log inactivation of *Cryptosporidium* down to 0.1 log should be explicitly stated in §141.729. AWWA strongly recommends that EPA provide similar equations expressing the log inactivation of *Giardia lamblia* cysts and viruses with chlorine dioxide.

4.2.14 Requests for Comment on Ozone and Chlorine Dioxide

Request for Comment
Determination of CT and the confidence bounds used for estimating log inactivation of *Cryptosporidium*.

Response
AWWA supports the proposed approach. See comments above.

Request for Comment
The ability of systems to apply these CT tables in consideration of the MCLs for bromate and chlorite.

Response
AWWA would characterize the proposed ozone CTs as difficult to achieve, given the requirement regarding low-temperature effects on CT and constraints imposed by the bromate MCL. Because primacy agency approval of plant designs is structured around worst-case design conditions, the ozone system will be designed around low-temperature conditions. Where the state requires the design to be based on 5º C or less, ozone inactivation is effectively limited to 1-log inactivation. In regions of the U.S. where water temperatures are warmer, then 1.5 to 2.0-log inactivation can be achieved at an affordable cost.

With respect to bromate, the level of inactivation achievable for any particular source water will be a function of source water bromide levels, whether or not the utility is using sodium hypochlorite (and if, so what grade of hypochlorite is available). AWWA is aware of water treatment facilities in the southwestern U.S. that will be unable to achieve the desired ozone CTs for 2-log *Cryptosporidium* inactivation and reliably comply with their internal goals for bromate control.

Request for Comment
<u>Any additional data that may be used to confirm or refine the proposed CT tables</u>.

Response
AWWA has submitted in the above discussion and in Appendix 10 an approach to expand the ozone CT tables to address synergistic disinfection from ozone-chloramine application and the available data.

4.2.15 Microbial Toolbox – Maintaining Compliance

The LT2ESWTR and associated guidance manuals have not directly or completely addressed important issues regarding requirements for maintaining a microbial toolbox credit, once awarded, nor the consequences of not being able to meet one of the requirements for a specific credit for a short time period (i.e., one month). The regulatory consequences of violation of the requirements for a microbial toolbox credit probably will entail a Tier 2 (30-day) notice. The final rule preamble and guidance should address the following questions:

1. How to identify or define when a violation occurs, and
2. Once a violation occurs, how long should consequences apply.

In order to ensure compliance many utilities will identify log credits greater than that actually required by the LT2ESWTR. Therefore, if one toolbox component does not perform adequately, and the associated log credit is not achieved, there is an extra 0.5- to 1.0-log credit "in reserve." An example utility on a New England lake needs to achieve 2-log credit to comply with the LT2ESWTR. This utility employs ozone, but may have difficult meeting CT in the coldest parts of the winter. The utility might employ the CFE and WCP tools to ensure a "reserve" of 0.5- to 1.0-log credits. The compliance algorithm for the LT2ESWTR should allow utilities to employ such proactive management techniques to ensure ongoing compliance.

4.3 Public Notice Provisions

EPA has correctly characterized violations of the additional treatment requirements for *Cryptosporidium* under the LT2ESWTR as subject to Tier 2 public notice requirements. The PNR language was changed to accommodate the provisions of the IESWTR with respect to *Cryptosporidium*. No additional changes are needed at this time.

4.4 Variance and Exemptions

Variance and exemption avenues are included in most SWTR rules, but the proposed LT2ESWTR forecloses the potential to apply for either. Given the agency's handling of the microbial toolbox, the microbial toolbox will likely not be an adequate substitute for including the variance and exemption reports. The situation is even more acute for unfiltered supplies that have few alternatives in the microbial toolbox. Primacy agencies should be given the flexibility to provide variances or exemptions from monitoring and treatment requirements under the LT2ESWTR. A practical application of these provisions might be oversight of unfiltered systems that are compliant under the LT2ESWTR but experience an excursion under the SWTR. This issue also raises the issue of simultaneous compliance discussed by the FACA. Ongoing compliance with DBP levels is a condition for filtration avoidance, so the possibility exist that Stage 2 DBPR provisions, rather than the LT2ESWTR provisions, would impact Filtration Avoidance status of unfiltered supplies. AWWA recommends that the agency extend relevant provisions of the SWTR to the LT2ESWTR.

4.5 Sanitary Survey Provisions

EPA proposes and requests comment on implementation authority to address significant deficiencies identified during a sanitary survey. The agency proposes two provisions (1) PWSs would respond to the agency in writing as to how and when significant deficiencies identified by

EPA would be corrected and (2) PWSs would be required to correct significant deficiencies. This proposal lacks two important components:

1. An administrative process in which a system could appeal a significant deficiency determination; and
2. A clear statement that the significant deficiency provision is NOT directly tied to MCL or determinations of a treatment technique violation.

5 Cost/Benefit Analysis

EPA has made progress by providing considerable discussion and sophisticated numeric evaluation of several of the uncertainties and variabilities (e.g., using Monte Carlo simulations) for some aspects of the analysis. On the other hand, EPA neglects to detail, justify, or fully explore some of the most fundamental of its assumptions. In the face of these core uncertainties, sensitivity analyses are essential for evaluating the impact of core assumptions at key junctures of the analysis. EPA needs to find a better balance by using more fundamental, informative, and comprehensive analyses of core components rather than using more sophisticated approaches for less critical aspects of its analysis.

Hence, at the core of our critique, is the message that EPA needs to take better stock of its analyses, determine what components are most critical in terms of driving the benefit or cost estimates, and focus its attention (and that of the reviewers) on those aspects. Models, analytic tools, and documentation should be presented in a way that facilitates understanding and review.

Stratus Consulting of Boulder, Colo., assisted AWWA's review of the EA and supporting documents. A copy of Stratus Consulting's report is attached as Appendix 12.

5.1 Communication of Uncertainty in the Cryptosporidium Risk Characterization

As arbiter of "sound science," the agency has a number of responsibilities when it communicates to the public. First and foremost among these responsibilities is being direct, honest, and transparent in its analyses and decision making processes. With respect to transparency in the LT2ESWTR rulemaking record, substantial documentation of analyses conducted by the agency is provided and information is provided that allows informed, interested parties to replicate the LT2ESWTR analyses. However, when AWWA reviewed the LT2ESWTR record, it was unable to conclude that the agency has been direct and honest in its analysis of the rule's benefits.

While SDWA makes provision for the LT2ESWTR to be exempt from the formal cost/benefit, health-risk reduction analyses required of most other rules promulgated since the 1996 SDWA Amendments, the agency has a fundamental responsibility to clearly articulate the costs and benefits of proposed and final rules. A clear accounting of benefits in the case of the LT2ESWTR would allow AWWA to better inform its members about the steps they will be required to take under the LT2ESWTR. It would assist the consulting engineering community and regulatory community in balancing competing design issues and defining regulatory expectations. And perhaps most importantly, it would assist EPA in articulating to the American public and its congressional overseers the impact of the LT2ESWTR. It would also help to direct needed research. The LT2ESWTR EA fails to provide a credible estimate of benefit from the proposal and in so doing, makes implementation of the rule more difficult and contentious. The EA may fulfill the letter of the agency's obligation to conduct certain analyses and relate them to the public. The agency has not successfully complied with the spirit of those requirements, which are intended to ensure that the agency provides a clear and logical explanation of the critical policy decisions and assumptions that underlie the rule provisions.

5.2 Davenport, Iowa, Study

A useful comparison EPA did not draw on in its EA is the recent Davenport, Iowa, study and similar work. Comparing the anticipated benefits from the LT2ESWTR with the findings of the fourth in a series of sound epidemiological studies that have failed to demonstrate a significant linkage between public health (including various forms of gastroenteritis) and tap water. The absence of strong correlation (the study had the power to discern a difference of 10% in disease burden between the controls and tap water consuming groups) is significant. This is the second large-scale, triple-blinded surface water epidemiology study to reach this finding (follows on Hellard *et al.*). While Melbourne draws its source water from a protected watershed and employs chlorination as its primary treatment mechanism, Davenport draws its water from the Mississippi River and operates a conventional plant meeting PSW Phase III criteria.

The absence of discernable disease attributable to drinking water exposure gives considerable pause to one reviewing the LT2ESWTR EA. Through an assumption-driven analysis, it estimates a disease burden that should be readily discernable in a well-funded study such as the one undertaken in Davenport by Colford *et al*..

5.3 Overview of the Benefits Analysis

Figure 3 is a flowchart of the factors affecting each step of the benefit analysis. When examining the issues identified in Figure 3, the risk reduction benefits developed by EPA may be overstated in many ways. Compounding the changes at each step as depicted in the figure, the overall estimate of benefits derived by EPA could be an order of magnitude or more larger than a more plausible and likely estimate.

5.4 Exposure Estimate

EPA's EA employs data and assumptions that, individually and cumulatively, significantly overestimate exposure. In predicting exposure, EPA does not demonstrate that the agency has explored critical assumptions nor that it has a clear and cogent rationale for those assumptions. The agency does not reflect on the compounding levels of conservatism in its analysis.

5.4.1 Occurrence Data

EPA uses data collected under the Information Collection Rule (ICR) and two subsequent smaller ICR Supplemental Surveys (ICRSS) to assess the presence of *Cryptosporidium* oocysts in source waters. Both sets of data were collected explicitly to support the LT2ESWTR rulemaking. Participants in the 1992 Reg-Neg process agreed to the ICR, and EPA developed the the supplemental surveys to improve the cost estimate for the rule.[69] Appreciable differences exist between the results generated by the initial ICR and the follow-up ICRSS. For example, the ICR data assign 7.6% of the systems into either bin 3 or bin 4, whereas the ICRSS assign an average of less than 1.2% of the systems to those bins — a difference factor of over 6.4 (7.6/1.2).

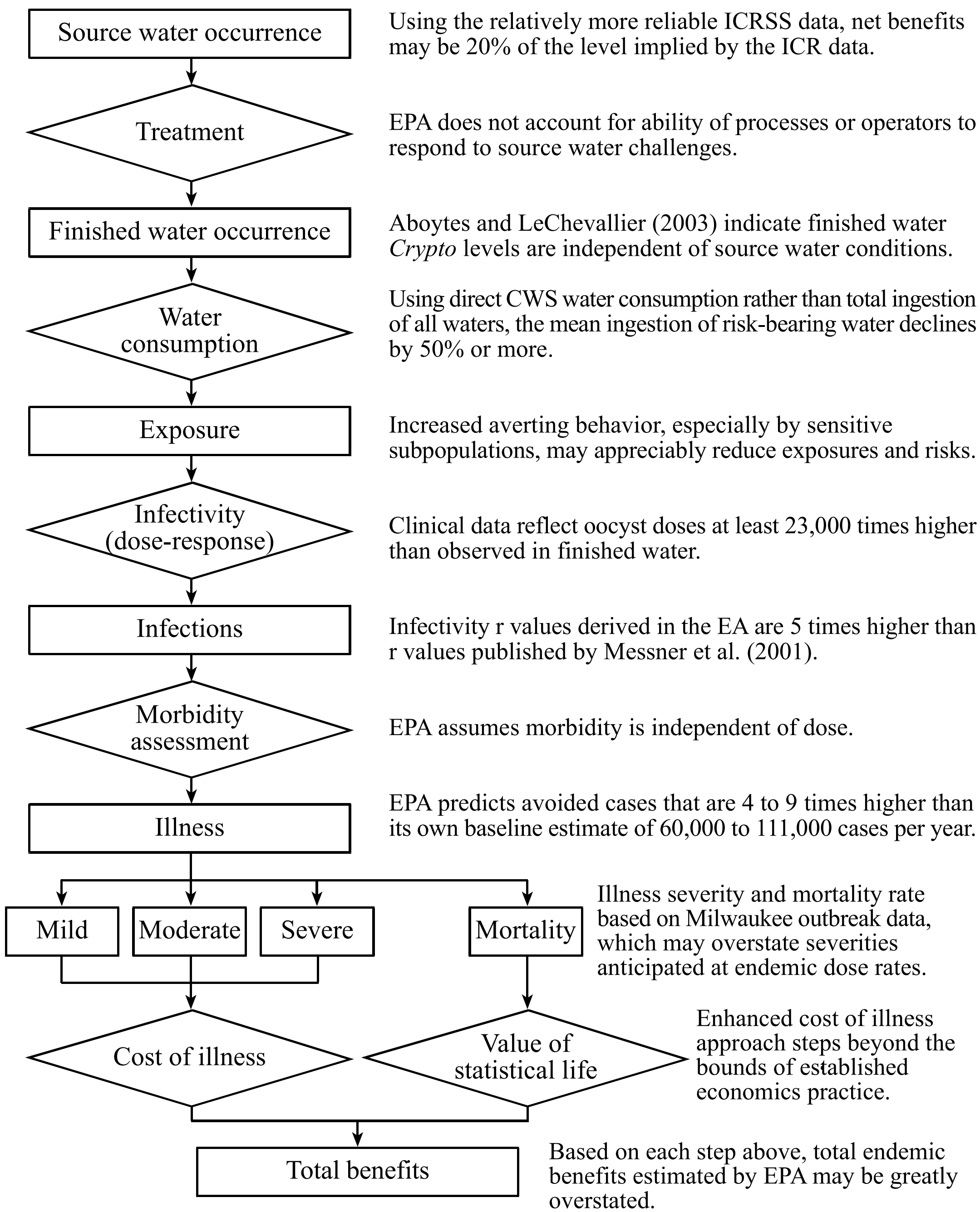
5.4.2 Occurrence Model

The conclusions EPA reached using Bayesian modeling are highly dependent on the assumptions made, many of which are not "prior knowledge." EPA should carefully document and justify these assumptions and opinions. It should also run sensitivity analyses and document them in

[69] See associated information collection request FR notice and information package.

ranges that a wide array of experts agree to. EPA should ascertain, communicate, and consider the effects on the rule and on the benefits of these assumptions.

Figure 3. Factors Affecting Benefit Analysis



Also, the ultimate objective is to better understand finished water quality. Thus, greater focus on monitoring finished water (rather than analyzing source water and then projecting finished water quality before and after projected treatment) seems to be a more suitable path for future investigation. Limited finished-water data suggest that oocyst levels may be more uniform across facilities, regardless of source water, than EPA projects in the EA.

Considerable uncertainty exists about the accuracy of presence/absence findings and numbers of oocysts derived in the ICR and ICRSS findings (more so with the ICR because of the lower recovery of the analytic method). For example, a high likelihood of false positives exists because of limitations in the IFA methodology. False positives would erroneously push more systems into higher bins. A large percentage of sample observations are zero oocyst counts. This may be because *Cryptosporidium* oocysts were not present in many samples and/or because recovery rates were low (especially for the ICR data). Positive samples were noted for only 7% of ICR sample observations (93% were zeros).

Because of its concern about the large percentage of non-detects and low and variable method recovery, EPA applied Bayesian statistical techniques to the ICR and ICRSS data. An integral part of the Bayesian approach is the use of "informed priors" that reflect what knowledge or outcomes the researchers believe to be true (e.g., using probabilities based on known data). The specific priors that are applied in Bayesian applications typically drive the outcomes that are derived from the analysis. In other words, the priors typically determine the outcomes. By way of example, EPA's model included a parameter for false positives (Z_i); the prior (assumption) was a value of at 0.001% or 0.001 depending on the reference in the EA (EPA staff have confirmed values employed was 0.1%). In discussions with individuals expert in *Cryptosporidium* analytical methods outside EPA, it appears that a false positive rate well in excess of .1% would be more consistent with expert opinion and that a more credible rate would be in the range of 25%, particularly for the ICR data. Changing this one prior (assumption) would dramatically change the distribution of oocysts predicted by the Bayesian model. Conversation with EPA staff suggests that this change is unlikely to affect the estimated occurrence of oocysts in the portion of the distribution relevant to the bin algorithm. This response is unsatisfactory. The use of priors that are not consistent with practical experience in the broader community raises concern with the analysis and cast doubt on the relevance of its outcome.

In the EA, EPA describes the true zero prior as "the true proportion of systems with source water that is completely free of the target microbe." This is not the definition of true zeros employed during the Stage 2 M/DBP FACA. As described to EPA by an impartial expert panel in 1999, zero observations are simply that, observations that are zero.[70] The assumption described above can be restated as an oocyst observations should almost never be zero. This is clearly a statement at odds with observations made in the ICR, ICRSS, and in subsequent monitoring, even monitoring using experimental molecular assays to identify *Cryptosporidium* oocysts.

Given that EPA's results are driven by assumptions (over which there was considerable disagreement with experts) rather than "prior knowledge," the agency must:

1. Identify explicitly and label clearly what assumptions are being used (i.e., identify them clearly as assumptions);

[70] M/DBP Statistical Panel Meeting Summary, December, 1999.

2. Provide a clear and cogent rationale why those assumptions are indeed reasonable and defensible;
3. Develop and/or accept alternative assumptions that are equally defensible or more plausible;
4. Conduct sensitivity analyses to understand and reveal how the alternative assumptions (priors) affect the outcomes of the analysis;
5. Present the results of the sensitivity analyses in a clear, objective, and informative manner; and
6. Use the results of the sensitivity analyses to inform the decision-making process (and document the same).

For example, analyzing the effect of using total *Cryptosporidium* oocyst counts from the ICR data versus non-empty oocysts versus oocysts with internal structure would be informative in understanding the logic behind why the total oocyst count was used in the occurrence assessment. Initial sensitivity analyses run during the FACA process suggested that total oocyst count is one log higher than the non-empty count, which is one log higher than the internal structure count. The probability of false positives is markedly higher with the total oocyst count compared to the non-empty and internal structure count. AWWA recommends that the agency give serious consideration to:

1. Reducing its reliance on statistical analyses that are by their nature difficult to understand and distinguish observation from assumptions.
2. Including a detailed description in plain English of the basis for any assumptions, use of sensitivity analyses, and results when it employs complex statistical procedures to describe those analyses; and
3. Checking its statistical analyses against expert observation, so that the results of the analysis are consistent with actual field experience.

5.4.3 Exposure Estimate

A fundamental component of the risk assessment and benefits analysis is the amount of tap water ingested by the public. The discussion above examines several concerns with the assumptions employed by EPA in this aspect of its EA. For example:

1. Accounting for exclusive use of bottled water by an increasing number of households would reduce the subsequent risk analysis and benefits results by approximately 20%.
2. Adjusting exposures to reflect direct ingestion in the home might reduce the risk and benefits results by another 50%.
3. Reflecting averting behavior by AIDS patients and other sensitive populations would directly and proportionally affect the largest component of the monetized benefits estimates.

While the drinking water intake values used in an analysis are not often the focal point of much scrutiny, the values used do have a very sizable impact on the ultimate risk and benefit findings. EPA should reconsider how it has approached this aspect of the EA, and provide improved and more expansive analysis and documentation. EPA needs to correct the EA to reflect the issues and data noted here.

To estimate the amount of water ingested per day, EPA uses data from the U.S. Department of Agriculture's (USDA's) *1994 — 1996 Continuing Survey of Food Intakes by Individuals* (CSFII). According to the EA, USDA provides two distributions of water ingestion levels:

1. "Distribution 1" is based on total water ingestion from all sources and has a median (50th percentile) level of 1.05 L/day and a 90th percentile of 2.35 L/day. EPA uses the mean from this distribution, 1.24 L/day, as the basis for its national-level risk estimates.
2. "Distribution 2" is based on water ingestion from CWS sources, and has a median (50th percentile) level of 0.71 L/day and a 90th percentile of 2.02 L/day. The mean from this distribution is 0.93 L/day (or 75% of the mean from Distribution 1 that is used by EPA as the basis for its national-level risk estimates).

AWWA believes it would be more accurate and reasonable to use the mean or median value from Distribution 2 instead of Distribution 1. This would result in risk estimates and benefits that would be 75% (0.93/1.05) or 57% (0.71/1.05) of the current EPA estimates, respectively, all else being equal. Distribution 2 reflects use of CWS waters by their customers, a more relevant use level for the regulation that is targeted on water utilities than "water from all sources," which includes bottled water, household wells, household rain cisterns, and household or public springs, in addition to CWS. Water from CWS represents approximately 75% of total daily water intake (U.S. EPA, 2000). Hence, Distribution 2 is by its definition a more suitable fit for CWS-relevant tap water exposure than Distribution 1.

Distribution 2 may also over estimate drinking water exposure. A recent EPA-sponsored Gallup poll (U.S. EPA, 2003c) and AwwaRF-sponsored research by Raucher et al. (submitted for publication) indicate that as of 2002, 75% of Americans drink bottled water, 14% to 20% drink only bottled water, 37% use in-home filtration devices, and only 49% to 56% drink exclusively tap water in their homes.

The ingestion levels for both USDA distributions as presented by EPA in the EA (U.S. EPA, 2003a, p. 5-23) are higher than applied or derived previously. For example, EPA's prior estimate of tap water intake (U.S. EPA, 1999) reflects a mean of 0.67 L/day, a median of 0.50 L/day, and a 90th percentile of 1.31 L/day. These are 72%, 70%, and 65%, respectively, of the same measures EPA now reports for Distribution 2 (and the mean from U.S. EPA, 1999, is 54% of the mean EPA now uses, as drawn from Distribution 1).

If one nets out the exclusive bottled water drinkers, and also reduces applicable daily intake for the remaining homes to reflect the nonrisk-bearing portions of current water ingestion patterns, then the overall result would be benefits at 40% to 43% of the levels currently presented in the EA. This implies that the EPA national estimates are quite possibly overstated by a factor of 2.3

to 2.5 (i.e., 1.0/0.4 = 2.5), simply on the basis of how much relevant tap water ingestion the agency assumes.

5.4.4 Dose-Response

The dose-response portion of the EA is a very complex and highly significant component of the overall analysis. Critical assumptions must be made at several points in the analysis because of pervasive scientific uncertainties. EPA makes several plausible and reasonable assumptions and inferences, but there are also components of the analysis where alternative assumptions or scenarios seem more plausible or, at a minimum, equally plausible. In such instances, the agency should be more explicit and balanced about the assumptions being made, and should conduct meaningful sensitivity analyses to reveal the impact of the alternative assumptions on the overall findings. Of particular concern from our review of the EA, are the following:

1. The estimation and use of r-values for inherent infectivity. The estimation process is not well documented and is poorly presented; the underlying data have significant limitations; and the results that EPA apparently uses are appreciably higher than findings published in the peer-reviewed literature. EPA should provide greater documentation, discussion, and review.

2. The morbidity assessment is dose-independent. Given the extremely high doses used in the clinical trials relative to the levels in finished water, and the evidence of dose-dependent morbidity in some studies, it seems prudent to at least conduct reasonable sensitivity analyses on the impact of this key assumption.

3. EPA's projected number of cases avoided is implausible given the baseline level of illness projected by the agency. In fact, EPA estimates of avoided cases are between 4 and 10 times higher than its baseline.

4. Morbidity levels, the allocation of cases across severity classifications, and the characterization of the duration and impact of illnesses in each severity class are all based on data from the Milwaukee outbreak of 1993. The use of data from a massive outbreak (with very high levels and durations of primary and secondary exposure) as a basis for estimating numbers, severity, and duration of illness from endemic exposures to far lower doses seems problematic. Here again, given the core uncertainties and the importance that these assumptions have on the final benefit outcomes, some alternative scenarios should be developed and assessed using sensitivity analysis.

Each of these limitations in the EA are discussed in greater detail in Chapter 5 of a report prepared for AWWA by Stratus Consulting evaluating the LT2ESWTR EA. A copy of the report is contained in Appendix 12. An implication of this report is that the use of obvious alternative assumptions in any of the above four aspects of the dose-response relationship would significantly reduce the morbidity predicted in the EA and consequently the benefit derived from LT2ESWTR.

5.4.5 Valuation of Health Effects

EPA's use of cost of illness (COI) based estimates to attempt to value the *ex ante* risk reduction WTP for cryptosporidiosis is understandable, given the lack of reliable data from which to infer the preferred measure of *ex ante* WTP. The agency's traditional COI is a reasonable estimate for EPA to use in this regard, and it may reflect a lower bound. The development and application by EPA of the "enhanced COI approach", which the agency characterizes as a surrogate willingness to pay analysis, is lacking in both credibility and plausibility. Differences between COI and enhanced COI approaches are enumerated in Table 4.

Table 4. Differences in the Valuation of Time in the Traditional and Enhanced COI Methods

Time category	Traditional COI valuation	Enhanced COI valuation
Paid work time	Median pre-tax wage plus benefits	Median pre-tax wage plus benefits
Unpaid work time (household production)	½ of median post tax wage	Median post tax wage
Leisure time	Not valued	Median post-tax wage
Sleeping time	Not valued	Not valued

The enhanced COI approach does not adhere to standard practice in the economics profession (e.g., with regard to valuing time spent out of the workplace), and it generates results that do not appear to be reasonable relative to other benchmarks, such as value of a statistical life (VSL). A simple illustration vis-a-vis *ex ante* willingness-to-pay provide a context to assess the reasonableness of the enhanced COI approach. VSL estimates reveal the *ex ante* willingness-to-pay of individuals to reduce risks of premature fatality. A VSL of roughly $6.3 million if often used as a measure of the value of reducing risks of premature fatality, based on a large body of well-reviewed literature in which individuals (e.g., median aged workers) in effect reveal a willingness-to-pay to reduce a mortality risk typically in the range of 1 in 10,000 per year. What this literature actually tells us is that a typical, median aged person has an *ex ante* willingness-to-pay of $630 per year, on average, to reduce a 10^{-5} risk of premature fatality in the coming year. This widely accepted $630 per person of *ex ante* willingness-to-pay to avoid a 1 in 10,000 annual risk of immediate fatality serves as our frame of reference.

The following illustrative example completes this comparison to a VSL estimate.[71] Lets assume that the risk posed by cryptosporidiosis was permanent and that symptoms were suffered through a recurring cycle of typically mild or moderate cases (with perhaps a rare severe episode as well, but no risk of fatality). Thus, a median aged worker struck by the disease under this assumption would face predominantly mild illness (and the associated COI) for the balance of his or her life. If one were to contend that EPA's enhanced COI approach provided useful and reasonable approximations of *ex ante* willingness-to-pay to avoid a lifelong case of cryptosporidiosis such as depicted in this example, then this implies an average *ex ante* willingness-to-pay of $455 per person exposed to the 1 in 10,000 annual risk of this version of the disease outcome. While this

[71] Stratus Consulting, Review of LT2ESWTR EA, Chapter 6 contains a detailed description of this illustratory example.

illustration uses a somewhat contrived version of cryptosporidiosis (lifelong continuous recurrence of a typical, severity-weighted nonfatal case), it does provide useful context for considering the valuation issue. A lifelong cycle of diarrhea and other mild symptoms would no doubt be unpleasant, and no doubt a typical person would be willing to pay a considerable amount to reduce the risk of such an outcome. However, would they have a willingness-to-pay that is over 72% of their willingness-to-pay a comparable level of risk of immediate fatality (i.e., \$455/\$630 = 72.2%)? This does not seem to be plausible or likely.

AWWA does not believe that the enhanced COI analysis should used to evaluate this rulemaking, and should instead be subjected to far greater peer review and revision before EPA attempts to inject it into any future matter of public health policy-making.

5.4.6 Special Populations

Exposure

In its summary of the risk assessment guidelines, EPA notes that "when the risks posed are not the same for all persons, that variability should be described." Further, the summary of guidelines notes that ideally these risks will be addressed through "the use of scientific data (or reasonable assumptions if data are not available) to produce estimates of the nature, extent, severity, and degree of risk" (U.S. EPA, 2003a; p. 5-4 for both quotes).

Using benefits estimates in the EA, Exhibit 5.24, AIDS patients account for 85% of fatal risk, and fatal risk reductions account for more than 67% of total benefits. These estimates are premised on the consumption of tap water — without any additional precautions — by these members of the sensitive subpopulation. For almost a decade, CDC, EPA, the water community, and AIDS organizations have been strongly and consistently encouraging AIDS patients to be aware that additional precautions are warranted regarding tap water. The EA should reflect this advice and the practical observation that this guidance has altered consumption patterns in the AIDS community.

Approach

In one respect, EPA's approach could be interpreted as being consistent with the previously summarized risk assessment guidelines because sensitive population subgroups are identified and separate outcome-based risks are developed for the subgroup and for the rest of the population. However, the health benefit estimates for the LT2 raise questions when considering how specific characteristics of the critical population subgroup (i.e., persons living with AIDS) that could influence the results are lost in the approach ultimately used.

Specifically, EPA makes adjustments to its mortality risk estimates to try to account for the distribution of persons living with AIDS in the United States, but the adjustment effectively assumes a uniform dispersion of persons living with AIDS in specific types of water systems. The clear limitation to this approach is that persons living with AIDS in the United States are not uniformly dispersed, but highly concentrated. Consequently the EA's analytical approach accrues benefits where the AIDS population in reality is not present in sufficient density to actually accrue the predicted benefit.

5.4.7 Affordability Based on System Size

We have not conducted a detailed review of EPA's cost estimates for the proposed LT2 rule. Nonetheless, it seems unlikely that the information provided regarding confidence intervals is realistic. EPA appears to have either ignored or understated many key uncertainties and variabilities appear to a considerable degree in order to generate a very narrow 90% confidence interval (only +/- 11% around the mean).

The lack of meaningful disaggregation according to system size is cause for particular, critical disappointment with the agency's cost and affordability analyses, and with the benefit/cost comparisons portrayed in the EA. The lumping by EPA of size categories serves only to mask and obscure important information regarding the equity and efficiency implications of the proposed rule. This is a serious flaw and a considerable disservice to the public, stakeholders, and decision-makers.

Finally, the agency's approach to comparing benefits to costs could be far more meaningful and informative if it also disaggregated the benefit/cost results in two important additional dimensions: (1) filtered and unfiltered system benefits and costs, and (2) the costs and benefits of the finished water reservoir cover requirement as embodied in the preferred option. The agency needs to do much better with regard to system size and other levels of disaggregation, and it would take only a modest effort on the agency's part to do so (if it musters the will).

5.4.8 Requests for Comment Regarding Economic Analysis

EPA poses three specific requests for comment with respect to the EA underlying LT2ESWR. Those three questions and responses are provided below (68 FR 47758).

Request for Comment
How can the agency fully incorporate all toolbox options into the economic analysis?

Response
The agency faces two significant hurdles in appropriately reflecting the costs and benefits of complete implementation of the microbial toolbox. First, application of the toolbox elements is site-specific and intimately related to both the existing water treatment facility design and water quality treatment challenges. Consequently, even an expert Delphi group process fully informed as to the final rule's regulatory requirements and guidance is unlikely to predict with any high degree of accuracy the range and extent of microbial toolbox application. It may be possible through a combination of survey and expert evaluation to prepare a reasonably accurate estimate of toolbox element application for the largest water systems (i.e., ICR utilities). As this group of utilities represents a significant fraction of the cost and accrued benefit from the rule, perhaps such an effort would be adequate for the agency's purposes.

An effort like that described above would not be possible unless the utilities surveyed and the experts involved had a very clear understanding of the regulatory provisions and final agency guidance. This approach, while capturing the bulk of the national costs and benefits of the rule, would not provide a sound approach for determining system level costs for small to medium sized systems. Because this group of systems is so large and the water quality challenges and treatment designs so diverse, reasonable estimates of cost and benefit are highly uncertain.

Utilities that make an investment in watershed control, RBF, off-stream storage, pre-sedimentation, enhanced filtration, and dual filtration are not simply adding a capital facility. These utilities are committing to an ongoing program that will improve influent water quality, improve the stability and reliability of the treatment process, and improve overall management/operation of the facility. The costs and benefits of these operational changes are not reflected in the simple selection of an add-on disinfection unit operation. Likewise, it does not reflect the ability of these unit operations to reduce either the challenge facing the primary treatment train or the enhanced removal of other contaminants, both known and unknown. For example, RBF is known to reduce organic contaminants entering the water treatment facility, off-stream storage allows for settling of particulates, and enhanced filtration clearly results in increased particle removal. The current EA's non-quantifiable benefits section is not reflected in Table VI-2 of the proposed rule and did not receive any substantive discussion in the EA itself. For the water supply community, these non-quantifiable benefits are the essence of the microbial toolbox, a substantial reason for supporting the LT2ESWTR proposal, and a critical aspect of the regulatory framework and guidance for the LT2ESWTR. AWWA believes that the agency has a responsibility to articulate the above benefits in the final rule preamble and reflect these benefits in the final rule regulation and guidance.

Request for Comment
How can the agency estimate the potential benefits from reduced epidemic outbreaks of cryptosporidiosis?

Response
LT2ESWTR is actually one in a series of rulemakings. In 1998, EPA promulgated the IESWTR, which established controls on water treatment plants employed by Subpart H utilities serving 10,000 or more persons. Shortly thereafter the agency promulgated the LT1ESWTR that expanded very similar regulatory controls to water treatment plants employed by Subpart H systems serving less than 10,000 persons. Both IESWTR and LT1ESWTR were explicitly intended to address reduction of epidemic waterborne cryptosporidiosis. The agency recognized in those rulemakings that epidemic waterborne cryptosporidiosis attributable to drinking water were principally associated with disruption of treatment. Consequently, those two rulemakings increased the rigor of the regulatory standard for turbidity at the combined filter effluent and set individual filter effluent reporting requirements that trigger systematic evaluation of the drinking water treatment facility. The central distinction between IESWTR / LT1ESWTR and LT2ESWTR is that LT2ESWTR is intended to address endemic waterborne cryptosporidiosis attributable to drinking water.

EPA has already implemented regulations (the IESWTR/LT1ESWTR) to manage epidemic outbreaks of cryptosporidiosis and estimated benefits from those regulations. Therefore, an estimate of additional benefits from epidemic outbreaks is not needed within the LT2ESWTR EA.

6 Miscellaneous Requests for Comment

Request for Comment
EPA requests comment on the proposed provisions of the inactivation profiling and benchmarking requirement. (68 FR 47718)

Response
AWWA is a signatory to both the Stage 1 and Stage 2 M/DBP Agreements. Both of these Agreements include provisions for risk balancing between DBP formation and disinfection. In the IESWTR the disinfection profiling and benchmarking provisions were explicitly written to address risk balancing during the implementation of the Stage 1 DBPR and IESWTR and LT1ESWTR. Extending this concept to LT2ESWTR is sound.

Request for Comment
Is it appropriate to allow systems with uncovered finished water storage facilities to implement a risk management plan or treat the effluent to inactivate viruses instead of covering the facility? (68 FR 47719)

Response
AWWA is a signatory to the Stage 2 M/DBP Agreement in Principle as is EPA. The Agreement in Principle specifies that either covering the reservoirs or the implementation of a risk management plan per the approval of the primacy agency are adequate remedies if treatment of the uncovered reservoir effluent is not provided. AWWA supports the Agreement in Principle including this provision.

Request for Comment
If systems treat the effluent of a finished water storage facility instead of covering it, should systems be required to inactivate *Cryptosporidium* and *Giardia lamblia*, since these protozoa have been found to increase in uncovered storage facilities? (68 FR 47719)

Response
Under the Stage 2 M/DBP Agreement in Principle, a risk management plan approved by the primacy agency is an adequate remedy for an uncovered reservoir. If treatment strategies are included in such a risk management plan for a particular uncovered reservoir, it should address the range of microbes for which treatment is necessary. The primacy agency can specify treatment for *Cryptosporidium, Giardia lamblia*, and / or viruses, if needed, depending on site-specific circumstances and the adequacy of other aspects of the risk management plan.

Request for Comment
Additional information on contamination or health risks that may be associated with uncovered finished water storage facilities. (68 FR 47719)

Response
EPA should review the docket of the IESWTR, and records of subsequent stakeholder interaction on guidance for uncovered reservoirs. These records provide a robust description of the issues relevant to uncovered finished water storage facilities.

Appendix 1. LT2ESWTR Treatment Requirements *Cryptosporidium* Monitoring, Bin Assignment, Core Treatment, And Microbial Toolbox, EET, 2003

[Document appended to comments as a separate electronic file.]

Appendix 2. *Cryptosporidium* Removal Credit Assignable in the LT2ESWTR Toolbox, EET, 2001

[Document appended to comments as two separate electronic files (Appendix 2a and Appendix 2b).]

Appendix 3. Summary of Relevant Articles Pertaining To *Cryptosporidium* and Watershed Control Program Effectiveness

AWWARF Studies

1. Source Water Assessment: Variability of Pathogen Concentrations (LeChevallier et. al, 2002)

2. Impacts of Major Point and Non-Point Sources on Raw Water Treatability (Pyke et al, 2003)

3. AWWARF Project 2671 – Development of Event-Based Pathogen Monitoring Strategies for Watersheds, currently under way.

4. AWWARF #251 – Evaluation of Sources of Pathogens & NOM in Watersheds (Kaplan et al, 2002)

5. AWWARF Field Transport of *Cryptosporidium* Surrogate in a Grazed Catchment, (Pennell et al., 2002)

WERF Studies

1. ·00-WSM-3 : Field Calibration and Verification of A Pathogen Transport Model. Montemagno, et. al, 2003, currently under way, contact Dean Carpenter at dcarpenter@werf.org, (703-684-2470, ext. 7152).

2. WERF 99-HHE-2– Sources and Variability of *Cryptosporidium* in The Milwaukee River Watershed. (Corsi, et. al, 2003).

3. WERF 99-HHE-1 - Methods to Detect *Cryptosporidium* in Wastewater (underway, lead researcher - Jennifer Clancy)

Pertinent Articles

1. Atwill, E. R., L. Hou, B. Karle, T. Harter, K. Tate, and R. Dahlgren, Transport of *Cryptosporidium* parvum Oocysts through Vegetated Buffer Strips and Estimated Filtration Efficiency. Appl. Environ. Micro 68(11):5517-5527, 2002.

2. Bradford, S. and J. Schijven. Release of *Cryptosporidium* and Giardia from Dairy Calf Manure: Impact of Solution Salinity. Environ. Sci. Tech. 36(18):3816-3923, 2002.

3. Dayton, E., N. Basta, C. Jakober, and J. Hattey. Using Treatment Residuals to Reduce Phosphorus in Agricultural Runoff. JAWWA 95(4):151-158, 2003.

4. Finstein, M., Watershed Protection: Review of Literature on Inactivation of *Cryptosporidium* in Manure. Submitted JAWWA, 2003 (in review). Contact finstein@envsci.rutgers.edu. (304-242-0341).

5. Gracyk, T. and J. Grace. Maryland Department of the Environment *Cryptosporidium* Occurrence Study in the Potomac River. Presented, November 5, 2003, AWWA Water Quality Technology Conference, Philadelphia, Penn. Also presented to EPA Headquarters in August 2003.

6. Suwa, M. and Y. Suzuki, Occurrence of *Cryptosporidium* in Japan and countermeasures in wastewater treatment plants. Water Sci. Tech. 43(12):183-186, 2001.

7. Suwa, M. and Y. Suzuki, Control of *Cryptosporidium* with wastewater treatment to prevent its proliferation in the Water Cycle. Water Sci. Tech. 47(9):45-49, 2003.

8. Stott, R., E. May, E. Matsushita, and A. Warren, Protozoan predation as a mechanism for the removal of *Cryptosporidium* oocysts from wastewaters in constructed wetlands. Water Sci. Tech. 44(11-12):191-198, 2001.

9. USEPA, Overland Migration of *Cryptosporidium* Oocysts – Final Draft Issue Paper. September 21, 1999. Contact: Mike Borst, borst.mike@epa.gov, (732-321-6631).

10. Rose, J, L. Dickson, S. Farah, and R. Carnahan. Removal of pathogenic and indicator microorganisms by a full-scale water reclamation facility. Water Research 30(11):2785-2797.

Appendix 4. Specific Comments on Draft Source Water Monitoring Guidance

EPA has prepared a number of individual documents that bear on source water monitoring. Specific items within these documents should be modified and inconsistencies between the various documents should be resolved.

General Comments

Guidance on Generation and Submission of Grandfathered *Cryptosporidium* Data for Bin Classification Under the Long Term 2 Enhanced Surface Water Treatment Rule contains recommendation missing from Source Water Monitoring Guidance Manual for Public Water Systems for the Long Term 2 Enhanced Surface Water Treatment Rule. The April 2003 guidance indicates that when there is chemical addition that interferes with a desirable monitoring location, one option is to discontinue application of the chemical feed and sample after the chemical has dissipated.[72] This recommendation is not found in the June 2003 guidance. While haphazardly stopping and re-initiating chemical feeds is not appropriate, circumstances could occur where this option may facilitate implementation. If this approach is a valid, the final guidance for source water monitoring should include this approach so that the primacy agency will have a clear signal that this is an appropriate practice. This clarity is particularly important where the primacy agency must provide *a priori* approval of such changes in chemical addition (i.e., changes that affect CT, achieving enhanced coagulation, etc.).

Specific Comments on WCP/Toolbox Guidance Manual

Page Section	Comment
p.2-6, 2.2.3	Giving credit to existing system SWP/WCP program efforts Requiring more effort -- in addition to what is already being done by an existing WCP -- is punitive and would prevent any program that could readily make any progress through WCP to reduce *Cryptosporidium* levels from using the WCP credit. EPA should reword the guidance to state that upon review, the state may determine that the focus of existing efforts could be redirected to other areas or that additional efforts may be necessary, but not required. For example, just because a system has a WCP in place and is observing source water concentrations over 0.075 oocysts/L doesn't mean the program isn't effective and needs more effort and resources. By agreeing to WCP, EPA recognizes that there are 10-20 year timeframes prior to observing true impacts on water quality. Planning, funding, constructing, and monitoring BMPs such as filter strips can take up to five years to accomplish at each site. Consequently, existing WCPs should be reviewed and credited appropriately for toolbox credit.

[72] Guidance on Generation and Submission of Grandfathered Cryptosporidium Data for Bin Classification Under the Long Term 2 Enhanced Surface Water Treatment Rule, April 2003, Section 3.1, p. 3.

Page Section	Comment
p.2-8, 2.2	<u>Watershed Sanitary Survey frequency should be 10 years</u> Watershed sanitary surveys should be required every 5-10 years at most. Even a fast changing watershed will not change in one year. The monitoring intensity needed to demonstrate watershed improvement will divert needed resources away from all other watershed protection program elements, including special sampling needed to support watershed program elements. Assimilating, compiling, analyzing, and evaluating information to determine effectiveness of actions and new efforts will require a 12-month effort to be done properly at least for larger watersheds.
p.2-9, 2.3.3.2	<u>Sanitary survey's conducted by approved persons</u>. AWWA recommends that states allow PWSs to conduct the sanitary survey if they desire in lieu of the primacy agency. AWWA does not believe the primacy agency has the financial or personnel time or expertise to implement this requirement effectively. By way of example, the CWA primacy agencies are behind in their efforts to assess all of the streams for impairment under the Clean Water Act.
2-39, 2.5.2	<u>The PWS should be allowed to have a representative participate in the watershed sanitary survey if desired or requested.</u> AWWA recommends that states allow PWSs to conduct the sanitary survey if they desire in lieu of the state. AWWA does not believe the states have the resources financial or otherwise to implement this requirement to the extent needed.
2-39, 2.5.3	<u>Removal of the "re-approval" process</u> The re-approval of the Watershed Control Program every six years is an added requirement by EPA that is beyond that required of any of the other toolbox items and violates the spirit of the Stage 2 M/DBP FACA agreement. EPA should eliminate the re-approval process and design the program so that systems need to gain approval only once. However, if the state or supervising agency identifies that the system fails to meet the requirements of the WCP plan or program, then the utility would not be eligible for the 0.5-log removal credit until the primacy agency re-approves the program. The inclusion of a six-year re-approval process in the WCP creates an upward spiral of requirements. This process is in direct conflict with current EPA approaches to watershed protection that are designed for steady and incremental progress. As it currently stands, even systems with the best watershed control programs currently in place would not consider the WCP option due to the uncertainty of re-approval every six years.

Appendix 5. Focused Review of Peer-Reviewed Literature as It Pertains to Issues Raised by Preamble and Guidance on Bank Filtration

[Document appended to comments as a separate electronic file.]

Appendix 6. Comments regarding LT2ESWTR Microbial Toolbox Guidance Manual – Bank Filtration

Section	Comment
4.2.1	Statement is made that each sample must be "examined" to determine grain size. This discussion should specify sieving by ASTM methodology.
4.4.2.3	This section is too general. Various methodologies for determining the extent of cementation are given, but the section does not define which are appropriate, nor who should determine what are acceptable levels of cementation. Does the agency with primacy? Rotary core drilling will likely give the most disturbed sample of any drilling methodology. Because samples are carried by a drilling fluid and then separated from the fluid, the sample will be exceptionally disturbed. How can core intervals be determined? Split-spoon samples collected in glacial settings with auger drilling may not be able to achieve the 90% core retrieval requirement. A single cobble can result in no retrieval from a particular core. The most efficient method for obtaining relatively undisturbed core samples is rotasonic drilling. It is likely to have the best retrieval percentage also. This should be included. Cable tool drilling in combination with split-spoon or Shelby tube sampling should also be discussed. The standards listed for design and construction of wells are acceptable, but a bit dated. Additional references are the NGWA 2nd Edition of Manual of Water Well Construction Practices, the AWWA Water Well Standards, Roscoe Moss Handbook of Water Well Development
page 4-28	After figure 4.5, there should be another section heading for the geophysics discussion. Geophysics may provide additional site exploration and supporting information, but cannot be used alone to determine the suitability of a site for bank filtration. The current methodology is not sufficiently refined to provide the level of detail required. There may be certain cases where geophysics alone can rule out a site (e.g., if it is determined that the site is exclusively bedrock, or cemented with fractures), but it cannot definitively determine that a site is appropriate for bank filtration. Geophysics are most effective when used in conjunction with exploratory boreholes, not in place of them.
page 4-30	It is incorrect to state that utilities will find it preferable and simpler to use the previously mapped limits of the 100-year floodplain to determine the edge of the river. In some river-aquifer systems, virtually all wells taking advantage of the induced infiltration are located within the 100-year floodplain. The wells would not be able to induce infiltration and in many cases would be outside the aquifer, if located outside the 100-year floodplain. By virtue of being located

near the river to induce infiltration increases the likelihood that the well would be located within the 100-year floodplain.

While the FEMA definition of floodway is a nationally recognized definition, its application will significantly reduce the number of utilities that can implement RBF without obtaining state approval for siting wells in the floodway or investing in significantly more expensive boreholes in order to reach productive portions of the aquifer.

The FEMA floodway is determined for the purpose of identifying where structures might impede flow during flooding and consequently where floodproofing measures are appropriate when building does take place. While it is a very convenient definition because of its wide availability, it is much less appropriate in context of bank filtration. Using the FEMA definitions can result in well locations that are not productive bank filtration locations. The use of the FEMA definition in the BF guidance is another reason why pilot well and full-scale demonstration of performance is an important complement to the criteria provided by EPA for BF log credit.

page 4-32 Research by Golnitz, et al., indicates that estimated ground water flow velocities during high river stage do not increase to levels that would be a threat to the riverbank filtration system. In fact, most estimated velocities were below or within the range for an engineered slow sand filter, even during high stage. EPA is not giving bank filtration its due ”credit” by making blanket statements that high ground water velocities can be a significant threat to a riverbank filtration system.

Appendix 7. References for Pre-Sedimentation Discussion

1. Cornwell, D. and M. MacPhee. 2001. Effects of Spent Filter Backwash Recycle on *Cryptosporidium* Removal. *JAWWA*. 93(4):153-162.

2. Cornwell, D., M. MacPhee, N. McTigue, H. Arora, G. DiGiovanni, and J. Taylor. 2000. *Treatment Options for Giardia, Cryptosporidium, and Other Contaminants in Recycled Backwash Water*. Denver, CO: AWWARF and AWWA.

3. Dugan, N., K. Fox, R. Miltner, D. Lytle, D. Williams, C. Parrett, C. Feld, and J. Owens. 1999. Control of *Cryptosporidium* Oocysts by Steady-State Conventional Treatment. *Proc. Of 1999 Annual Conference.* Denver, CO: AWWA.

4. Dugan, N., K. Fox, J. Owens, and R. Miltner. 2001. *Cryptosporidium* Control Through Conventional Treatment. *JAWWA*, forthcoming.

5. Edzwald, J., and Kelley, M., 1998. Control Of *Cryptosporidium*: From Reservoirs To Clarifiers to Filters. *Water Science and Technology*. 37(2):1-8.

6. Edzwald, J., J. Tobiason, L. Parento, M. Kelley, G. Kaminski, H. Dunn, and P. Galant. 2000. *Giardia* and *Cryptosporidium* Removals by Clarification and Filtration Under Challenge Conditions. *JAWWA*. 92(12):70-84.

7. Hall, T., Pressdee, J., and Carrington, N. 1994. *Removal of Cryptosporidium Oocysts by Water Treatment Process*. London, England: Foundation for Water Research Limited.

8. Patania, N., J. Jacangelo, L. Cummings, A. Wilczak, K. Riley, and J. Oppenheimer. 1995. *Optimization of Filtration for Cyst Removal.* Denver, CO: AWWARF and AWWA.

9. Plummer, J., J. Edzwald, and M. Kelley. 1995. Removing *Cryptosporidium* by Dissolved-Air Flotation. *JAWWA.* 87(9):85-95.

Appendix 8. Review of UV Disinfection Guidance Manual Evaluation of Validation Protocol, CH2M Hill

[Document appended to comments as a separate electronic file.]

Appendix 9. Technical Memoranda from Process Applications on k* and CT_{10}

a. Memorandum to Steve Via from Kerwin Rakness, October 21, 2003, Rejecting and retesting for >20% k* variance.

b. Memorandum to Steve Via from Kerwin Rakness, December 8, 2003, Extended-integrated CT_{10} calculations (w/ supporting electronic spreadsheets)

[Documents appended to comments as a separate electronic file.]

Appendix 10. Segregated Flow Analysis Guidance

[Document appended to comments as a separate electronic file.]

Appendix 11. Technical Memoranda from Water Quality and Treatment Solutions on Synergistic Inactivation Between Ozone and Chloramines

a. Memorandum to Steve Via from Issam Najm, December 4, 2003, Synergistic Inactivation between Ozone and Chloramine (Synergy Analysis)

b. Memorandum to Steve Via from Issam Najm, December 4, 2003, Synergistic Inactivation between Ozone and Chloramine (Response to Questions)

c. Chloramine Synergy Database WQTS (Excel File)

[Documents appended to comments as a separate electronic file.]

Appendix 12. Review of LT2ESWTR Economic Analysis, Stratus Consulting

[Document appended to comments as a separate electronic file.]